THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

convenes the

ADVISORY BOARD ON

RADIATION AND WORKER HEALTH

The verbatim transcript of the Meeting of the Advisory Board on Radiation and Worker Health held at The Garden Plaza Hotel, 215 South Illinois Avenue, Oak Ridge, Tennessee, on May 19, 2003.

VOLUME I

C O N T E N T S

May 19, 2003

TRANSCRIPT LEGEND

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TANKERSLEY, BILL
THOMAS, BRIAN
TOOHEY, R E

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P R O C E E D I N G S

(9:10 a.m.)

REGISTRATION AND WELCOME

CHAIR

DR. ZIEMER: Good morning, everyone. I'm going to call the meeting to order. This is meeting 16 of the Advisory Board on Radiation and Worker Health. My name is Paul Ziemer and I serve as Chair of the Board.

Let me begin by welcoming all of you to Oak Ridge, and I feel I can do that in a valid way since this is my old stomping ground. I spent the first year of my marriage actually here in Oak Ridge, and last night Marilyn and I drove up to the old apartment. I don't think I'd want to live there anymore. I don't think they've painted it since we left, many years ago.

In any event, welcome to Oak Ridge. It's great to have all of you here, some local folks as well as those who've come from out of town.

We'd like to remind you to, if you haven't already done so, to please register your attendance with us this morning. There's a registration book back on the table

where Cori Homer is standing back there, and we ask that all of you register, whether you're Board members, staff, government staff people, members of the public or others.

Also if you are a member of the public and wish to participate in the public comment period later today, we ask that you sign up so that we have some idea of how many do wish to address the Board during that public comment period.

I'm not going to introduce the Board members to those who are observers, but the Board members names are on the placards, so you can see who they are. I see that there is an empty seat. Is Mike Gibson not going to be here today?

MR. ELLIOTT: He's here somewhere.

DR. ZIEMER: He's here somewhere. Okay, so the record will show hopefully at some point that we have a full attendance of the Board. And also, as Board members or other speak, we do ask that you identify yourself so that the recorders are able to make a record of that as the transcript is prepared.

There are a number of items on that table over here on

my left which include everything from the charter of this Committee to minutes of past meetings and other documents. So if you are interested in any of those, we invite you to make yourself -- or help -- help yourself to those, and I'm walking around looking for a piece of paper that I set aside. But if there are documents that you wish, those are all available. Help yourself to those.

We have a special privilege this morning and a special guest that I want to introduce, and that is Dr. John Howard. Dr. Howard is the Director of the National Institute for Occupational Safety and Health, NIOSH, and we're very pleased that he is with us this morning. Prior to becoming Director for NIOSH, Dr. Howard served as chief of the Division of Occupational Safety and Health in California's Department of Industrial Relations, a position he held since 1991 until his more recent appointment as Director of NIOSH. In that capacity in California he headed up an occupational and public safety program that involved a staff of nearly 1,000, so quite a large operation there.

Prior to his appointment as NIOSH Director, Dr. Howard

also was an assistant professor of environmental and occupational medicine at the University of California at Irvine, and he's also served as medical director and chief clinician of the Philip Mandelker AIDS Prevention Clinic, which is an AIDS community clinic in Los Angeles. He's also been assistant counselor to the Undersecretary of Health and Human Services.

Dr. Howard began his career in occupational health as an internist for the University of California, Los Angeles School of Medicine on a pulmonary fellowship program at Cedars-Sinai Medical Center in Los Angeles, and during his clinical work he worked very closely with asbestos-related situations, particularly asbestos-exposed shipyard workers, and his work has been published on occupational lung disease related to asbestos exposure.

He did his doctoral work in medicine at Loyola University and has a Master's in occupational health from the Harvard School of Public Health, and has other academic degrees and many other credentials that I won't go into today. In fact, already my introduction is probably longer than what he's going to say because

he's going to simply give us a brief greeting. So with that, Dr. Howard, welcome and we're very pleased to have you with us today.

DIRECTOR NIOSH

DR. HOWARD: Thank you, Dr. Ziemer, and it is -- your introduction is definitely longer than what I was going to say. I just wanted to express my appreciation for -- for all of the work that you do here on the Board. When I first came to my job in July, I received periodic e-mails about your meetings, and I thought after the fourth or fifth one in rapid succession, I though my, these people actually do work. And so I just want to compliment you on your dedication and professionalism and all the hard work you're doing with this program, and to assure you that, even though I've been very tardy in getting here to one of your meetings, I'm very interested in what I'm going to learn in the next two days. And certainly I've been exposed to all the issues that you all are struggling with through -- through Larry and others in the program. So I just want to say that you have the full support of the Institute and the Institute leadership,

as well as the Department of Health and Human Services in the work that you're doing.

So thank you for having me here today and I hope to learn a lot over the next couple of days. Thank you.

DR. ZIEMER: Thank you again, Dr. Howard. We also provide an opportunity for Larry Elliott from -- our Executive Secretary, to make any opening comments. And Larry, if you have any, this is the time.

EXECUTIVE SECRETARY

MR. ELLIOTT: Thank you. I just want to welcome everybody to Oak Ridge. It's nice to see a good crowd, and I look forward to a productive two days. And I hope everyone has an interesting and informative two-day meeting. Thank you.

DR. ZIEMER: Now we're going to turn our attention to our regular program status report. Dave Sundin of the NIOSH staff is here with us again, and Dave, if you'll come -- there he is -- and present your summary to us.

PROGRAM STATUS REPORT

MR. SUNDIN: Is the podium mike on, the lavaliere? Can you hear me back there?

Well, I'll also say good morning and welcome to

beautiful Oak Ridge. I think this is probably the 13th face-to-face meeting. Paul mentioned 16 meetings, I believe is the count, counting the teleconferences. But in any case, clearly an active Board.

I wanted to present a brief overview of the program status. I'll use the basic approach that we've used in previous meetings.

Department of Labor has transferred over 12,000 cases to NIOSH for dose reconstruction since we began receiving cases in October of 2001. Actually close to 13,000 by now. These statistics are as of last Friday.

As you're probably aware, we continue to send a letter, a fact sheet, a brochure and a refrigerator magnet to each claimant, to let them know that we've received their claim. And we also explain to them in those materials what dose reconstruction is and how they can contact us to monitor progress. Recently we've modified this initial contact letter to include the name of a specific public health advisor who is available to provide specific information on their claim. The letter now also introduces and explains ORAU's role in the process, and we provide the ORAU

toll-free telephone number.
Of course we log each case into our computerized claims tracking system. We electronically scan all the documents in each case file, and we also create and maintain a paper file system. We've been making some significant improvements, and in particular recently, some improvements in our database management systems and connections to permit us to operate more efficiently and exchange information appropriately with ORAU, our contractor.
You can see that the majority of claims involve employees who worked at DOE sites, but about 16 percent involve employment at Atomic Weapons Employer sites, or AWE's.
This chart shows the rate at which we've been receiving cases from the four district offices of DOL by month. The number of cases peaked at 1,031 in August of 2002 and has trended generally downward since then. I think it's probably too early to determine whether this is a short or a long-term trend, however.
Each case file we receive from DOL does list the verified covered sites where the Energy employee

worked, and so we use this information to direct our requests for radiation exposure information to the appropriate DOE points of contact. In some cases, of course, the employee may have worked at several covered facilities. We're usually able to issue these requests for DOE exposure information within two weeks of receipt of the case from the Department of Labor. We've sent out nearly 12,000 requests for personal radiation exposure information to our DOE points of contact, and we've received responses to 63 percent of these requests. Some of these responses we know contain incomplete information, which means that follow-up requests to DOE for additional information will be required before dose reconstruction can proceed in those cases. About 20 percent of our requests are more than 60 days outstanding, and these cases are highlighted in a periodic e-mail status report that we send to each of the DOE points of contact and the DOE Office of Worker Advocacy.

This table shows how many requests for personal exposure information are going to I guess what you'd call the Big Eight DOE offices, and how many responses

we've currently received. And as you can see, the Oak Ridge operations office has received more requests and provided more responses than any other DOE office by a considerable margin, almost two, two and a half times, perhaps, of the -- as the Savannah River site.

We continue to work closely with DOE's Office of Worker Advocacy and the designated points of contact at the sites to ensure that we get the kind of exposure information needed to conduct dose reconstructions in a timely manner. And I will say that DOE has facilitated our participation in periodic teleconferences with their points of contact and the records retrieval staff at each of the sites, and they have also taken specific steps to add resources and improve the processes at certain sites.

As you probably know, a telephone interview is offered to each claimant to permit them to add information which may be relevant to reconstructing the radiation dose, and the award of our support contract has substantially increased our capacity to conduct interviews. And until a recent office move temporarily interrupted the work of the interviewers, or at least

slowed it down, their monthly production was climbing steadily. As of today we've conducted interviews with more than 2,600 employees and survivors. This chart, I should say, doesn't include a significant number of interviews that actually were conducted in April and May and which will be logged into our system when the interview group gets reconnected.

We have conducted several secure interviews using appropriately-cleared interviewers in a secured location to address concerns raised by the claimants. I am happy to be able to report to you that the number of completed dose reconstructions being sent back to Department of Labor for final adjudication is steadily increasing. Nearly 300 cases are currently assigned to a health physicist for dose reconstruction, and draft dose reconstruction reports have been sent to claimants in 137 cases. Seventy-three of those have been approved by the claimants and returned as final dose reconstructions, including a complete -- and have been sent to Department of Labor, along with the complete administrative record. Six of those final cases represent claims from Oak Ridge.

While we know that every performance measure is significant in this program, we're particularly pleased to see the number of completed dose reconstructions and dose reconstructions assigned actually begin to rise. We know we've got a ways to go before we achieve the more than 200 dose reconstructions per week target that we need to actually begin to make progress against our current backlog, but we feel like we're on the path and making progress.

We want claimants to be able to contact us, and they continue to do so. The number of phone calls received in OCAS has increased substantially each quarter as we receive more and more claims. We're currently receiving approximately 80 phone calls per day, and we've responded to nearly 30,000 calls since the program was launched in October, 2001. Some of those calls are related to setting up and actually conducting interviews, but the majority of them really are claimants and their representatives checking on a claim status.

Our web site continues to be a valuable source of up-to-date information about the program and a vehicle for

communication with claimants and others interested in EEOICPA. We've received over 1,600 claim-related e-mails, and our goal is still to respond to every one of them within 24 hours.

I'd like to draw your attention to some recent developments and accomplishments which I think are worth noting. Our Memorandum of Understanding between HHS and DOE was signed by the Deputy Secretaries of both Departments on April 4th, 2003, and that document is available on both the DOE and HHS-OCAS web site for your review.

As you know, the public comment period for our proposed Rule for adding classes of employees to the SEC closed on May 6th. And in addition to the Board's comments, the Docket Office received comments from 16 other groups and individuals and we're now considering all those public comments.

DOE has periodically asked that we appoint additional physicians to their physician panels which have a role in evaluating claims under Subtitle (D) of EEOICPA. We recently transmitted a list of 33 additional physicians to DOE, which brought the total number of appointed

physicians to nearly 80, and we will be appointing approximately 30 more physicians soon, and will continue the process of seeking out and identifying qualified candidates for these panels.

In late March OCAS approved a Technical Basis document which had been developed by ORAU which established the basis for developing an exposure matrix for the Bethlehem Steel Corporation in Lackawanna, New York. This document, which is also available on our web site, will permit us to complete virtually all of the approximately 435 Bethlehem Steel claims.

Also, and this is not news to most, a solicitation for proposals has been issued for contract technical support to the Board's review of the NIOSH dose reconstruction program following a pre-proposal conference which some of you attended in Cincinnati on April 30th. These proposals are due in the NIOSH contract office I believe May 28th.

And we continue to add the staff necessary to achieve the numerous tasks which are in front of us. OCAS currently has 35 employees in Cincinnati and three additional staff assigned to support our efforts from

Atlanta and Washington, D.C. We are in the process of recruiting to fill a few remaining vacancies. ORAU currently has more than 170 full-time equivalents on their staff.

As required under our contract with ORAU, we've negotiated production goals as part of our plan to reduce the backlog of claims which are awaiting dose reconstruction, and this plan calls for completion of nearly 6,000 draft dose reconstruction reports this calendar year, and that's through developing a capacity to produce a minimum of 200 dose reconstructions per week by July.

So I thank you for your attention. I'll try to answer any questions you might have at this point.

DR. ZIEMER: Thank you very much, Dave. Let me begin by asking a question of the third slide, which is cases received from DOL by month, and it has 2001, 2002 and 2003 in there, if you see that slide. It's a bar graph.

MR. SUNDIN: Right.

DR. ZIEMER: I don't know if you can back up to it, but it doesn't appear to me that there's enough months in

there to correspond to those years. Am I seeing something here? It seems to me there ought to be approximately 12 bars per years, if my advanced mathematics are correct.

Okay, it's starting in mid-year, so the year is not -- the year's in the middle, I gotcha. Okay. Now I should have figured that out.

MR. SUNDIN: So it runs from October 2001.

DR. ZIEMER: Either that or it's a Federal year or something here. Okay. A leap year. So 2002 is centered on -- so I can use any six bars to the right and left and I've got a year. Is that what you're saying?

MR. SUNDIN: January of 2002.

DR. ZIEMER: Okay. What I'm going to claim then is 2003 isn't centered on its year. It's -- okay.

MR. SUNDIN: I'd better re-graph this one.

DR. ZIEMER: Okay. Well, it wasn't clear what months was there. Okay. Thank you.

Other questions? Yes, Jim.

DR. MELIUS: I have some questions on your progress with the number of DOE sites. I don't happen to

remember all the numbers, but I think Savannah River, Idaho, some of the other sites seem to have an awful large percentage of claims that were -- or say significant at over 150 days. What are you doing to resolve those and how are you -- what are you doing to sort of track progress and get those back on board?

MR. SUNDIN: Right. Well, the story behind each of those sites is slightly different. We are working with the Office of Worker Advocacy and the site personnel themselves, but without going into a lot of detail, the story at Idaho, for example, involves the need to index a lot of records that simply have not been indexed so we expect that once that sort of front-end task is completed, then the rate at which we get responses will increase a lot.

Pick another site, Jim. There is a story behind each one of them and it's different.

DR. MELIUS: Savannah River, is that --

MR. SUNDIN: Yeah.

DR. MELIUS: -- one that you're having problems that looks like it's maybe getting better?

MR. SUNDIN: It is.

DR. MELIUS: I don't remember --

MR. SUNDIN: It is, and that is exactly the story. They were a little bit I guess -- shall we say slow getting out of the blocks, but in terms of the kind of responses we're getting from them now, we believe they're reasonably complete and they have added additional staff, in fact, to start being able to move their output up. So I think there it was just a question of them not getting started as early as some others.

DR. MELIUS: And how do you communicate these issues to the claimants? I mean 'cause you have -- I don't know, say 1,000 or more claimants that are sitting there -- it's been close to six months where they've been just basically not -- sitting there, the claims have.

MR. SUNDIN: Well, we always tell the claimants exactly what the situation is, as best we understand it. And we do tell them that the targets we establish for DOE response is 60 days, and some sites are able to meet that, some sites are not. We can tell each one of the claimants exactly how many days that their response has been with the DOE. We can tell them if we have gotten

a response, let them know that. But in terms of providing -- and we also tell them what we know about that particular site, what they're doing to help improve that response.

DR. MELIUS: But do you proactively -- do you communicate with them? I mean -- I mean a lot of these people, you know -- it's a difficult process and if they're sitting there -- they don't ask you what happens, I guess is my -- my question.

MR. SUNDIN: Well, we have -- I mean there is some information on our web site which sort of bears on this issue. We haven't profiled each individual site's response profile like this on our web site, and we have not gone out with mailings to claimants to sort of keep them updated. We're considering that, but -- so it is on a case-specific basis as people call in.

DR. MELIUS: Seems to me that if this is going to be a recurrent problem that some communication -- I mean the claimants deserve some communication. If they haven't heard from you in, you know, 90 days or 60 days or whatever on a -- you know, what's happening with their claim, I think they deserve some communication, you

know, from you about what's going on -- the problem is getting dose information or you've requested more, whatever that -- that's going on or that's delayed getting the program started and whatever. But it seems to me that that would be the least you could do, rather than let -- you know, have them sit there trying to figure out what's going on.

DR. ZIEMER: And Larry's got a response also here.

MR. ELLIOTT: Yes, Dr. Melius, we certainly agree with you and we think the claimants do deserve recurrent contact from us on a regular basis. We are -- as Dave said, we're considering how best to do that. We're targeting the groups that we need to reach out to, those that were the early claims. We're working up the communication vehicle that we're going to use for each of those targeted groups.

I would offer this, though, that the majority of those callers that we get are really a minority of the whole claimant population. We hear frequently from claimants, and in that minority there is a relatively few that contact us. But we're not losing sight of what you're suggesting, that even though we're not

hearing from the majority of the claimant population, we need to maintain our contact and our dialogue with them, and we are working toward that end.

DR. MELIUS: It's just precisely that that worries me. It's this -- the people you don't hear from are the ones that I think also deserve some communication from you. I have some other questions, but why don't you let somebody else go on and I'll --

DR. ZIEMER: Let's get -- I think we had Roy and then Robert and then Tony.

DR. DEHART: Roy DeHart. My question addresses this estimate of 6,000 dose reconstructions completed by, I assume, the end of the calendar year, '03. Is that realistic? We're talking about only seven months remaining, essentially, to accomplish that task.

MR. SUNDIN: Yes, I think it is realistic. There's been a lot of groundwork put in place that will, we believe, permit us to achieve those kinds of goals, and those goals were developed in discussions and full consultation with our contractor, ORAU. So it'll be a big rise. It'll be a challenge, but much of what we've been doing now is put the machinery in place to change

that level of production.

MR. PRESLEY: Dave, Bob Presley. Could you elaborate a little bit on some of the problems you're having in Oak Ridge with the records?

MR. SUNDIN: Well, it's one of the better sites, Bob. I think they've done a good job of responding to this high volume of requests that we've gotten. In terms of having a general sense of the quality and completeness issues, if any, I don't have that because I'm not really in the stream of reviewing them. There aren't a huge number of severely late cases out of Oak Ridge, so I -- I would have to say that on the whole -- you know, unless others want to correct me -- I would say that they're not problem-free. There've certainly been cases where we've had to, you know, give them a notice that this is overdue, but I would say that they've been very responsive.

MR. PRESLEY: Thank you.

DR. ANDRADE: Tony Andrade from Los Alamos. I agree with Dr. Melius that there should be some kind of communication. However, if the communication simply states that the dose reconstruction effort is awaiting

dose records and leaves it at such, you potentially are in a situation in which you are slamming a site. In our -- at our laboratories, for example, one employee may have had film dosimetry, a two-chip thermoluscent -- thermoluminescent dosimeter, and now we're using the six-chip TLD. On top of that, there could have been neutron dosimetry, track-etch* dosimetry and then dosimetry for various types of isotopes. So when you ask for the records for one employee, it is not a trivial process in many instances to recover the data and then deconvolute the data from committed effective dose equivalent back down to annual dose. So I know that, on a per-person basis, it is a -- somewhat of a task to send back precisely what NIOSH is looking for. So all I -- all I say is that that communication, if it's too simplified, can give the wrong impression.

DR. ZIEMER: Jim, you had another question?

DR. MELIUS: I have some more, but I think Mark was ahead of me.

DR. ZIEMER: Oh, I'm sorry, I didn't see Mark, but we have a response from Jim Neton.

DR. NETON: This is Jim Neton from NIOSH. I'd just

like to comment that we are ramping up -- ORAU's ramping up with the dose reconst-- I mean the computer-assisted telephone interviews, as you saw, so we've completed almost 3,000 interviews at this point, so claimants are being directly contacted by us. They are contacted in writing prior to the interview, and they receive a follow-up summary of their interview after that. The rate at which ORAU can accomplish interviews is now around 1,000 a month, so I think you'll see that many of those early claimants will be contacted in the near future directly by NIOSH.

DR. ZIEMER: Thank you. Okay, now Mark.

MR. GRIFFON: Yeah, just a follow-up on some of -- on the 6,000 cases question and -- you mentioned that a lot of the groundwork has been laid for -- you know, to make this -- to make that possible. I'm wondering about the site profiles, if -- and you might not be able to give us a status report, but I'm curious if we can get some status on the -- maybe before the end of this meeting, a status report on where the site profiles stand across the board. I think the last time we saw them, they were -- well, very -- very differing,

depending on the site. Some had a lot of information, some had very little, so I'm just curious where that stands.

MR. SUNDIN: I didn't bring that into this presentation, Mark. There probably are -- well, Jim can give you more details. I know that some of them -- several of them are being worked on.

DR. NETON: I can comment in general, and we're not prepared really to discuss the exact sequence of the site profiles at this meeting, but we are moving forward with the exposure models, as you noticed last -- two meetings ago, I believe, where we discussed the Bethlehem Steel model. There are two flavors of site profiles or Technical Basis documents, as we call them. One is an exposure model, which is what was done with Bethlehem Steel, where there were no bioassay data, no individual monitoring data, so ORAU was -- relied on the air sample data that was available and generated distributions about some central tendency of exposure for that model.

The other type of site profile would be the actual data where we have bioassay monitoring records and those

sort of pieces of information, and we are fleshing out the detection limits and monitoring frequencies and those sorts of things.

We have in house a completed site profile -- a draft site profile for Savannah River site. That's being reviewed by our staff now and we hope to have that finalized within the next month or so. There are a number of other site profiles that are being developed in parallel. We're not -- this is not a linear effort, so there is an entire group devoted to doing nothing but Atomic Weapons Employer site profiles, and there are other groups assigned to the various -- to the larger sites where we can cover I think 90 percent of the claims with something like 20 or 21 site profile documents. And so that's -- that's the plan right now. But the only completed draft in-house we have is Savannah River, and actually there is a Bloxon Chemical Atomic Weapons Employer model we're also reviewing at this time.

DR. ZIEMER: Thank you. Mark, follow-up on that?

MR. GRIFFON: Yeah. I guess the -- the main reason I reflect on this is that, you know, one of the concerns

that we've heard for years is -- is the concern with dosimetry data. And coming into this Board, I think we've -- we've discussed this issue, and my fear is that, 6,000 cases pending, that there's going to be -- I guess certainly it seems that you're going to turn to dosimetry data first, but in order to test the adequacy of those dosimetric records for purposes of this program, I think there has to be some site profile information, some site data to -- to make sure that -- that you're not just using already-suspect data to -- to make a conclusion on a compensation claim. So I think that was one of the central themes coming into this program. There was a lot of concern about dosimetric records and I think, you know, we -- there should be a lot of attention paid to that.

DR. NETON: Yeah, I would comment that we don't take any dosimetry information at face value when it comes in. I mean we -- we do investigate it and make sure the individual monitoring results were of sufficient technical quality to be able to reflect the conditions in the work place. Although I do agree there are some scenarios that are more complicated than others, but I

think that if we can validate the bioassay monitoring record, monitoring record -- monitoring program, and the film badge or TLD monitoring program, I think we can go ahead and work with that at face value if it appears to be a valid measurement.

DR. ZIEMER: And Jim, you have another question?

DR. MELIUS: Yeah, back to the -- a couple of questions, actually, but first of all, back to the progress on the program. It's very hard for us -- at least for me sitting here to get a handle on the hang-up. Why's it taking so long to get the program going, and it's I think equally hard for the claimants, as well as, you know, the number of members of Congress that have expressed some concern recently about the -- how slow the process has been. And we keep hearing that you're going to gear up and so forth. I just quite don't understand what the hang-up is over the last -- you know, what's holding up progress for the last few months in this program. You've staffed up with your contractor, yet it seems that we have, at most, 200 or 300 claims that are sort of close to being completed in the process that are out for review that

you're reviewing. And I can't tell -- is the issue the contractor, is the issue the -- your staff? You know, are you adequately staffed yet in order to be able to handle all these claims? And I guess -- you know, I hear number of going for around 6,000 by the end of the year, I really find that hard to fathom, given what's gone on so far with the program, particularly to maintain some quality and so forth to it. So am I not understanding something about the process or --

MR. SUNDIN: Well, I just -- I think -- it depends on what you focus on to measure progress. Certainly, as I said, we're all happy to see the end product start to come out the pipeline, but I would say that we've -- being on the inside of the program, working shoulder-to-shoulder as I do day to day with some very highly motivated people, that they're doing the very best they can on behalf of all claimants. I would say that there's been a substantial amount of progress made to basically lay the groundwork and develop the processes which lead to what I think many people focus on as the sole progress indicator, which is completed dose reconstructions. So I don't -- I don't --you know,

this is a program which came into being and had to be -- a whole organization created, so I -- I think we've made very good progress in getting to where we are now.

DR. MELIUS: Then can you just tell me in more detail what your -- what has been the progress? Is the -- is all this time spent getting set up, as you say, or whatever -- are you adequately staffed to be able to handle the number of claims coming over to you, review them? 'Cause I think that's -- you know, we -- you've described what the contractor's doing, that's -- may be fine and so forth. But how about at the NIOSH -- staffing, 'cause that's also another potential bottleneck and you really didn't provide much detail on where you stand with that.

MR. SUNDIN: Well, I indicated we're at about 35 people right now and recruiting for a few more vacancies. I think we've designed the organization to basically provide enough health physics capability to review each and every completed dose reconstruction, a sufficient number of public health advisors to be able to interact with claimants and to handle the case referrals when they come from DOL and then submit them back, and

certainly we've got some IT professionals that are working with us to develop the very most efficient database system that we can. So I would have to say that we've -- we've sized our staff and our organizational plan to -- appropriately to meet what we think the -- what the requirements are going to be at the kind of production level that we're anticipating.

DR. MELIUS: Do you have a system that tracks each claim and can tell you statistically where you -- where it is in the process and where things are getting slowed down, if they're getting slowed down? I mean we're getting bits and pieces of a tracking system here, you're -- you know, when it goes out for dose records.

MR. SUNDIN: Yes, we do. We've got a really pretty good system, which is evolving as we identify new needs for it. But yes, we can track each claim through all of the significant steps that a claim goes through on its way to completion. And that system, of course, can drive management reports, as needed, and all the other kinds of uses that one makes of that kind of data. So yeah, we have a fairly detailed system of tracking each

claim.

DR. MELIUS: And if I'd be correct, then four months ago that would have shown that the hold-up was at the interview end, getting people out to interview and -- and getting claimants interviewed. Now it would appear to be getting from the interview into a final dose reconstruction and review. Is that...

MR. SUNDIN: Well, I mean that is the way the pig moves through the python. At the outset there were a lot of claims that weren't even automated, that then a DOE request had not been made. So as each claim is with us longer, then it progresses more toward the end of the process. We do have significantly more interviewers doing interviews right now, so that -- that trend as you see is going up fairly sharply. There will be a lag between that and the dose reconstructions as these claims then find their way to a dose reconstruction. So I don't know that there's any single hang-up. I think we've got things sort of balanced. It's just that the life cycle of a claim will lead to more things being done on claims that are supposed to be done early on a claim than later.

DR. ZIEMER: All right. Henry, you have a question?

DR. ANDERSON: Yes, I just wanted to get a bit of information on the -- on what you're going -- or what your strategy is for those that are now getting out to the 150-day plus as far as information on those. It would seem to me some of those may well be ones that'll end up with incomplete records and would be a special cohort person and -- and my question really is at what point do you decide that, you know, you now need to go into a secondary strategy as to how -- you know, are we ever going to find records on these people. So part of it is, do you know how many of those are simply that the specific sites haven't gotten to the record so you don't really have any information on it, or have they started, gotten records and said boy, there really ought to be records on XYZ, but we can't find them yet and so they're continuing to hunt, in which those are going to be the more problematic than it's simply a massive backlog and they don't have the staff to begin the process, so those are sitting there basically cold, waiting to get started, versus those they've processed to a certain degree and they have some records but

there should be more and they haven't located them yet and at some point you're going to have to close the system off and say now then these are -- those go into a Plan B as to how we're going to deal with them.

MR. SUNDIN: Sure. No, good point. We obviously don't want endless searches to go on when there's no prospect of finding something. So far I don't believe we've had many responses from DOE that said I have exhausted -- we have exhausted all of our search strategies and have found nothing, end of story. But that's clearly what we need to call for at a certain point. Many of these sites that we believe are on productive searches or indexing strategies that will actually yield information, but clearly at some point we need DOE to tell us that they've reached the end of that line, and we've not gone back with that sort of call yet to any sites.

DR. ZIEMER: I'd like to ask the staff if it might be doable at our next meeting to give us a little more detail on the site profile issue, perhaps a more formal update on that. Is that something we could schedule for the next meeting?

Do we have additional questions for Dave at this point?

DR. MELIUS: I have one --

DR. ZIEMER: Jim, yes.

DR. MELIUS: -- or two separate issues. One is on -- and I may not be recalling this correctly 'cause I -- you don't have in in the table -- the DOE Memorandum of Understanding went out. I recall when I read that it surprised me a little bit, there was a -- something in there to the effect that each completed dose reconstruction would -- applied in individually-identified form, would go to DOE also?

MR. SUNDIN: Yes.

DR. MELIUS: What's the basis for that?

MR. SUNDIN: It's statute.

DR. MELIUS: Okay. Secondly, at one of our recent meetings we talked about conflict of interest statements being up on the web site for Oak Ridge AU staff, and when I looked at the web site recently it looked like at least half of them were missing. Is that an --

DR. ZIEMER: Who can --

DR. MELIUS: -- issue or something?

DR. ZIEMER: -- respond to that?

MR. SUNDIN: You're looking at the ORAU web site?

DR. MELIUS: Yeah.

DR. ZIEMER: ORAU's web site? Dick Toohey, can you respond? Or Jim?

DR. TOOHEY: Dick Toohey, ORAU. We're hanging them up right now. What happened -- and I'll freely admit, I dropped the ball on that one. A couple of meetings ago we had a request to change that form to include atomic weapon employer development, so we sent new forms out to all the people. We have gotten them back in and they are -- I think they're all scanned now and being hung up there on the web site, so they should all be out there for the people directly involved in dose reconstruction. You know, we're not putting them up for computer programmers and folks not directly involved in the dose reconstructions themselves.

DR. ZIEMER: Understood.

DR. MELIUS: And then finally one request for our next meeting. Could we get a more detailed way of presenting the progress in terms of these claims, where things are in the process, number of claims at each

stage and so forth and what progress is being made, 'cause I just find it very hard to -- give us snapshots and it's very hard to see where -- how things are moving through the process or where there are potential problems. Understand -- I mean I'm not asking for a response.

DR. ZIEMER: Yeah. They would need to identify how to do that in terms -- you're asking for how many are at this stage -- we're seeing some of the stages. You're asking for the intermediate points, I think.

DR. MELIUS: And there may be different ways of presenting it. I don't -- 'cause things are changing and apparently rapidly, so I -- but...

DR. ZIEMER: Perhaps in terms of the framework of the questions that have been asked, you get the sense of what's being asked for.

MR. SUNDIN: Yeah. No, I do. I made a note of it, Jim, and if you -- certainly if you have any preferred formats, let us know.

DR. ZIEMER: We do need to move on here. We have a very full agenda for this meeting. Let me move us forward. We have a related report on the DOL,

Department of Labor's status on their part of the program. We're going to hear from Shelly Hallmark -- Shelby Hallmark. Shelby has been with us before, but let me just remind you all who Shelby is. He was named Director of the Office of Worker's Compensation Programs for Department of Labor in June of 2001. He had been Deputy Director of that office beginning back at about 1990, and also served a couple of times as acting director, but now is the Director of that office.

He's been with the Department of Labor since 1980. He had a whole series of assignments over the years, starting -- or including responsible positions in Employment Standards Administration's Office of Management, Administration and Planning. He's also served as Chair of the Secretary of Labor's Strategic and Performance Planning Work Group in '98. He led the Department of Labor's 1999 to -- well, really current, I guess, to 2004 Strategic Plan, and its year 2000 Annual Performance Plan. So Shelby, we're pleased to have you with us this morning to give us an update on the Department of Labor's part of this program.

DOL PROGRAM STATUS REPORT

MR. HALLMARK: Thank you for that overly-long introduction, Dr. Ziemer. Even I wasn't interested in that stuff.

(Laughter)

All right. Well, it's a pleasure to be here, and I asked Larry if I could make a few remarks here this morning for the Board because I think it's useful for you to hear about where the ultimate product of -- at least the Part B portion of the Act is standing. And we're in pretty good shape. We're obviously further ahead than NIOSH is in the -- as we move along the process of cases moving down this line.

Am I coming through back there? Is that okay? All right.

Basically we have a fully functioning program now. We are in a posture where we've worked out our relationship with NIOSH and with DOE, with Justice, Social Security, unions, contractors. There's a lot of different groups to be dealing with, and I think that's one of the challenges that we all face in this program in trying to pull together a very large number of

players. We're pleased to say that we have a great relationship I think with all of the groups that are listed, and in particular with NIOSH. They've worked extraordinarily closely with us and we're pleased with that.

Energy has come along, and in answer to your question, Mr. Presley, about Oak Ridge earlier, we're pleased that we've been getting faster responses on our requests for records as we go to the sites, and especially at Oak Ridge where we have obviously a big volume. So the whole system is now at a point where it's working much more effectively.

We've gotten about 42,000 claims, and you'll see data in this -- in these charts that are both listed as claims and as cases. Obviously there are -- each individual person can file a claim, and so if you have a survivor claim, there could be five claims, all associated with one worker, which would be what we call a case.

We've paid out about half a billion dollars now, a little over the $562 million or thereabouts.

We have about 300 Federal and contractor workers

involved in our program in sites around the country, most of them in our district offices and our national office, between our legal folks -- they count as people, too, you know -- just barely. And our final adjudication branch, which is spread all over the country, also.

As I say, we've got about 42,000 -- almost 43,000 claims now. We have received about 8,000 claims so far this fiscal year, since October. We expect to get about 12,000 to 18,000 by the end of September, which is a big spread. And this slide indicates my expectation that as NIOSH cases come out of the pipeline, we will see an upsurge in cases. We don't know that for sure. We've had some indications, but it's possible that we'll have another upward blip. This is a quick refresher on the types of claims we've had, and you probably can't read these tiny little print in the back, but the yellow is cancer. That would be both SEC and NIOSH dose reconstruction cases, about 28,000, 29,000. Beryllium is about 2,000. That's sensitivity. About 1,800 CBD claims, about 800 silicosis claims, under 5,000 RECA claims and a very

large number of other, which are basically -- this 19,000 or so are basically folks who filed Part B claims who really are entitled to Part D claims, and that's taking the wrong door, basically.

There's our break of claims by employees, living workers and survivors, and as you see there, it's mostly survivors, 57 percent.

This is status of our cases right now, and this is a slide I think I showed back in Santa Fe, which -- and I'm proud of the changes that we've made here. In Santa Fe you'll remember we had about 20-some-odd -- 27,000 cases over here on the right, total cases, but we had about 8,000, 9,000 cases in the pending status, which meant our district offices were still doing something about them. Now that's 3,000, so that's less than ten percent, and we're looking at basically new cases that have come in in the last few months that are in that pending action category. Then they move across to the final -- they actually -- they go to a recommended decision, then they either go to a final decision or to the far column over there, which is sent to NIOSH. Those are the two possible outcomes that

we're looking at pending a NIOSH decision. So you can see we're in -- we're fairly current at the present time in our process.

This is just a slide that gives you a basic -- a little breakout of the types of cases that are in that 19,000 that I pointed out earlier which are not covered under our Part B program. A lot of lung cases, some just other other, which -- a compilation -- heart cases, asbestosis, COPD, renal failure -- even hearing loss, which in that case I think hearing loss doesn't even apply in most cases to the Part D situation.

This is just some basic program data, where we are in various different categories. Obviously we keep a lot of data and can give the Board more if you'd like to see it. This is a figure that I have pointed to in the last time I spoke with you, which is that we still are not paying very many medical benefits. That's about $10 million out of a total of $562 million in benefits, and that's -- suggests that we probably should be paying more, that people are not bringing the claims to us for medicals.

This gives you another breakout of the outcomes of our

final decisions. As you see there, 11,000 denials, the -- I believe that's purple bar is the other. That's the not covered conditions. Again, that's that group of cases that really should have gone through the other door to Part D. And so that's really skewing our outcomes. These are the sort of traditional worker compensation issues -- is the person really an employee of one of the covered places, is it a survivor who is eligible under our program, can they link the condition to the employment, is there sufficient medical. Those are the kind of traditional Workers' Comp denial categories beyond the ones which come in as basically the wrong door.

So this is our outcome level right now. I think when I showed you this slide in Santa Fe it was the other way around. It was 60 percent approvals, 40 percent denials. Now it's 70 percent denials, 43 percent approval. If you take out the Part D cases that came to us that are not applicable, that approval rate goes up to 70 percent.

And this tells you something about the timeliness of our processing. We have established goals for two

different categories of cases. One is our -- the basic DOE contractor site and RECA, which is 120 days down here (indicating). And the other -- and the up above is the AWE, beryllium vendors and subcontractors, which is up at the top. And our goals were 120 days for the straight -- what we thought would be straightforward cases and 180 days for the more complicated cases where we have to go searching for employment records. And as you see there now we're meeting those goals on average, 178 days for the AWE beryllium and 113 days plus for our DOE/RECA cases. And I -- that's been a -- hard-fought to get to that point, and we are getting better every day.

Of the cases we've gotten back from NIOSH -- and our numbers are a little bit different. I don't know, there may be some cases in the mail, Larry, I'm not sure. Our folks, as of last week, told me we had 48 cases back from you. If there's another 25 out there, we're glad to get them, too. There's 135, by the way, in full disclosure, which we've gotten back because we sent it to NIOSH and it didn't require a dose reconstruction, either the -- there are some cases,

like CLL, which early on we decided were in a different category, did not receive a dose reconstruction. And other cases where the individual, for example, may have later been determined to be part of an SEC and so there was not a dose reconstruction required, or the claimant died or other kinds of circumstances. So there's some that have come back to us for those reasons. And then -- but of the 48 that we've gotten back, we've accepted 80 percent at the first recommended decision level. We've accepted 13 out of 14 at the final level -- it takes a little while to get from one step to the other -- but we're anxious to get the rest of them.

As you've heard this morning, we expect to get 6,000 dose reconstructions through the end of this calendar year, and we are gearing up to accept them. We have a target of completing the first stage, the recommended decision, in three weeks of the receipt of the case from NIOSH, and I think we can meet that. And then the time from the time you get a recommended decision to when a final decision is issued can vary, depending on what the outcome is and how long the claimant takes to consider his or her options, but that won't be any

different than it is now. And we will -- as my last bullet says, we will move our cases around as we need to, because we expect to get clumps of cases. Our cases are geographically split among our four offices in Seattle, Denver, Cleveland and Jacksonville. We expect that because of the site profile approach, NIOSH is going to send us largely clumps of completed dose reconstructions which may overwhelm an individual office and that'll require us to distribute the workload to make sure that we meet these goals we have to move these cases through very promptly.

Just a few statistics about our cases that come in from Tennessee, about 5,600 cases so far. You see there we referred 2,300 to NIOSH, recommended decisions on 3,000. We've paid 1,500 claimants here in Tennessee about $167 million.

And this just shows you briefly what the status of those cases are. This is similar to the earlier slide. Of the 5,600 cases only 445 are pending, and that means you're current with workload coming in the door. The cases in Tennessee are mainly cancer, but a fairly good number of beryllium sensitivity and chronic

beryllium disease, 51 silicosis cases there and 2,000 other, which are the -- you know, Part D cases, basically. The silicosis cases could be in effect Part D, people who have filed the wrong thing, because only miners at the Nevada Test Site and Amchitka are eligible for benefits for silicosis per se under this program, although these people could have been there and moved to Tennessee, so that's a possibility, also. And I just show this slide, this is -- this shows a little bit about our expectations of claims receipts, and these data on the left as far as worker population came to us from DOE long ago. I think David Michaels gave us these. And I don't know that they are absolutely correct. They certainly don't include the whole penumbra of subcontractor and in some cases construction workers, and so that number may be low in that respect. But you see the number of claims we've received in the three different Oak Ridge sites and the percent of the population that has claimed. And these percentages are a little higher than they are in some areas, some other sites, but much lower, for example -- and interesting that K-25 is seven percent. Paducah's

similar plant is 36 percent of the known population has filed, and Portsmouth is 14 percent. So that's interesting in terms of the possibility that there may be other claims out there in the Oak Ridge area which are -- which could come in and which are possibly eligible cases. Again, given the vagaries of the estimation of the population, that's not a high science.

Just this last slide to say that we are continuing to do outreach, and the previous slide suggests that. We are -- we expect that there are other people out there who could file, and I don't expect you to be able to read that fine print back there. Don't strain yourself. But we're trying to do a lot of things. We still have our resource centers that are delivering help at the sites, including here in Oak Ridge. We have traveling resource centers. We're trying to get them out to as many locations as we can where we don't have a permanent office to try to address needs of people who haven't come forward. We're working with unions and other groups who have lists or information about people that we might contact directly. We're

trying to do things with media, public service announcements, that sort of thing to get words out to people who are not even close or no longer affiliated with any of the communities or unions or other activities. And we have our web sites, et cetera, et cetera. So we're looking for ways to try to improve our outreach so that we make sure that everyone who is in fact eligible for this program comes forward. We don't want people to come forward and file claims who are not eligible, but if they are, they have a possibility, we want them to know about it and we're looking for as much help from as many different sources as we can -- as we can find.

And that's, in a nutshell, where we are with the Department of Labor so far. Can I answer questions?

DR. ZIEMER: Yes, thank you very much, Shelby. Who has a question? Okay, Roy first.

DR. DEHART: Roy DeHart. Would you better define Part D and specifically does it include mechanical injuries, such as backs, necks, that sort of thing?

MR. HALLMARK: Part D of course is the part of EEOICPA that is administered by the Department of Energy and

Tom Rollo*'s group. As I understand it, Part D covers occupational illnesses caused by exposure to toxic agents, and I believe their regulation defines toxicity as not including such things as hearing loss and other sort of mechanically-conceived injuries. I think they did include toxicity -- they did include radiation as a toxic substance, although that I guess is -- there's some debate -- definitional debate about that, but that is included as part of the array of cases that you can take to the Part D portal. And everyone should understand that Part D -- individuals who are eligible for Part B are also eligible to apply separately to DOE under Part D, so you can go both ways.

The other column that I was citing to are people who are not eligible for Part B at all. They may be eligible for Part D, and you should know that as we receive cases and claims from those individuals, we inform them on a regular basis -- oh, you filed a claim for asbestosis; we don't cover asbestosis, these people over here do. And we give that information to them.

DR. ZIEMER: Jim and then Rich.

MR. ESPINOSA: He answered it.

DR. ZIEMER: Oh, he answered your question. Okay, Jim then.

DR. MELIUS: Okay. I hope Dave or Larry will find the missing 25 cases and let us know.

MR. HALLMARK: We hope they're -- they're coming soon.

DR. MELIUS: They're in the mail, right?

MR. ELLIOTT: Well, let me answer that right now because I signed 12 finished ones last Friday, so there is a lag time between us and getting them to DOL, so they're not only in the mail, they're there.

DR. MELIUS: We just want you to know we're keeping -- keeping an eye on you.

What is the -- you may not -- I don't know if you know this or not, but with the SEC claims, what's the trend been with them? Have they seemed to be going up, going down in terms of numbers filed and...

MR. HALLMARK: I can't say for sure because our -- the data that I see on a weekly basis is split out by site, but they don't -- there -- there could be claims in Paducah or Portsmouth that are either dose reconstruction cases because they have a cancer that's not one of the -- one of the 22 that's listed in the

statute, or they could be beryllium or they could be, you know, other things. So I'm not sure. I will say, though, that Paducah's volume of claims that have been coming in has stayed high. In part I think that's -- just reflects the fact that our resource center and the assistance that we get from PACE and other folks in Paducah is really intense there and so we find, for example, there's more -- there's more focus and more outreach to subcontractors I think in the Paducah site than some of the others. It's hard to say. I mean the percentage I showed there for Oak Ridge is six to seven percent. I think in Hanford it's four percent. So there are some sites where it's very, very low, and that's four percent against a number of employees in Hanford that doesn't even count any construction workers, and I've heard estimates of as high as 100,000 construction workers out there. So Hanford is very low. It's hard for us to know what the -- you know, what all the socioeconomic and other kinds of factors are, but we're trying to swim against that and see if we can't get people to come forward who in fact are eligible.

DR. MELIUS: Well, certainly at the SEC sites people are getting compensated so --

MR. HALLMARK: There shouldn't be any --

DR. MELIUS: Whereas the other claims that are not yet are at a very, very low rate, so --

MR. HALLMARK: That's right.

DR. MELIUS: -- that certainly gets -- word gets out and --

MR. HALLMARK: But as I say, it's clear that -- if these data are anywhere near accurate, it's clear there are a lot of K-25 employees who either haven't filed at all or, you know, maybe they -- you know, maybe because the population was older here, you know, they've dispersed and they just haven't gotten the word.

DR. MELIUS: Right, yeah. No, no, I think -- and I agree that there's a lot more outreach that can be done for these. One of the concerns of the Board has been people that might have -- be sort of partially eligible for an SEC. They worked, you know, some number of days there, but not enough to be eligible at a particular site, but then would have time at another part of a DOE complex, either another part of the site that's not SEC

eligible or at another site that's not an SEC site. And there's really -- it raises some difficulty in terms of how do you do dose reconstruction and so forth. Is there any way within your system of keeping track of that -- or maybe NIOSH can, I -- you know, those claims I assume would come in for an SEC -- initially identified possibly as an SEC. Then if it's discovered that they don't meet the employment requirement, do they -- do they get tagged in some way when they go over to NIOSH 'cause --

MR. HALLMARK: I -- I don't know. Pete Turcic, who is the director of the Energy program, is sitting back there, may be able to answer this better. It's my -- I don't know how many would fall into that category, but clearly at the point that we made the judgment that there were less than 250 work days that would qualify the individual as an SEC recipient or claim, we would then start to process it as a NIOSH referral. And whether that -- you know, whether we have any kind of tag on it that says this was a partial SEC or not, I don't know. Pete?

MR. TURCIC: Yes, we can track those claims, and we do

send them to NIOSH for a dose reconstruction. I believe we have some 400 or so claims, like from Paducah, for example, that are in for dose reconstructions.

DR. MELIUS: Okay. 'Cause I mean one of the -- on Larry's long list of things to do, I mean, one of the issues is that there is some regulation-related things that have to be dealt with that haven't been addressed yet with those, and I was just trying to get a sense of, you know, is it a priority or -- you know, are there many of these? I expect there'll be a fair number of them, just given the nature of employment at these sites and so forth.

MR. ELLIOTT: I don't have the numbers at my disposal right now, but we need to make sure we're clear on this. There are two types of claims here. There is those that are SEC but non-presumptive cancer claims which are sent over to us to do dose reconstruction.

DR. MELIUS: Right.

MR. ELLIOTT: And in that category, they may only have that site. Then there's this other category where they worked at an SEC site but not for the full time period

required, and they may have worked at other sites. That's the category you're getting at with your comment about dose reconstruction and our regulation. Yes, we can track both of those. We do track both of those. We can identify them in our tracking system as to which claim fits into which category.

MR. HALLMARK: And I would assume that of the 400 that Pete just suggested from Paducah that the vast majority of those are in the other kinds of cancer category as opposed to less than 250 work days. Now again, Paducah's done a better job of finding subcontractors and so they are more likely to have ferreted out people who were on-site for a small period of time or maybe intermittently over a long period.

DR. ZIEMER: Mark Griffon has a question.

MR. GRIFFON: Just a follow-up on some data, and I don't know if you keep this kind of data, but curious if you had any statistics on the types of cancers and -- overall and then broken out by site.

MR. HALLMARK: Cancers, as in primary?

MR. GRIFFON: Yeah, number of claims, type of primary cancer.

MR. HALLMARK: Yeah, we have --

MR. GRIFFON: Do you track --

MR. HALLMARK: I don't have it with me, obviously.

MR. GRIFFON: I mean is that something that can be provided to the Board possibly?

MR. HALLMARK: Yes, absolutely.

MR. GRIFFON: And the second is, do you -- do you track job categories or job -- job titles is interesting. Job categories would be more interesting to me.

MR. HALLMARK: That's not an element of our data system, and it's one that's very difficult to get your arms around, but we do -- you know, obviously we do have the cancer data.

DR. ZIEMER: Other questions for Shelby? There appear to be none. Thank you very much.

MR. HALLMARK: Thank you.

RECENT IREP MODIFICATIONS AND RECOMMENDED UPDATES

DR. ZIEMER: Now we're going to move to an update on IREP and some recent modifications and updates. We have two individuals with us today from SENES. One is Brian Thomas. Brian basically is a nuclear engineer. He's got his undergraduate and graduate degrees from

the University of Tennessee. He specialized in health physics, risk assessment, uncertainty analysis. He's had over ten years of experience in qualitative uncertainty analysis, extensive experience in developing and programming complex computer models, including the IREP model -- or the NIOSH-IREP model. And also let me introduce the other individual, who is Iulian Apostoaei -- is that close enough? And --

MR. THOMAS: I think Apostoaei would be the --

DR. ZIEMER: Right. We don't know whether we're using an American pronunciation or Greek or whatever, but Dr. Apostoaei is very experienced in radiological assessment, and actually did his doctoral work involving the uncertainties of internal dose factors from ingestion of Strontium-90. He's used the most recent ICRP models and is currently developing computational tools for determining acute and chronic intakes from plutonium -- or for bioassay data from plutonium intakes, estimating doses. This was a project I think originally came out of the University of Colorado and supported the epidemiological studies of the Rocky Flats workers.

He's also been involved in dose reconstruction projects at Idaho National Engineering Laboratory and for CDC. He's worked on some of the historical Iodine releases here in the Oak Ridge area, estimating doses of risks from cancer from exposures in the Hanford area, so a great deal of work involving dose reconstruction, epidemiological tables -- radioepidemiological tables. He's one of the main authors of IREP, so we're very happy to have him here today and please give us the recent modifications and updates and related --

MR. THOMAS: We'll certainly do that. Thank you for those introductions, Dr. Ziemer.

Let me start by saying that this projector system is really fancy and organized and -- so I applaud whoever thought of this idea to have all presentations on the same machine -- real streamlined. The only downside to this is that we had to have our talks ready two or three weeks ago, and this -- just so you know, this kind of goes against our longstanding tradition of making last-minute changes at midnight before a talk, so midnight rolled around last night and it felt weird.

Okay. Iulian and I are going to tag team on this

presentation. I'm going to first take you through four changes that have been made to IREP over the past -- actually these changes just got made, but IREP hasn't changed for, as you know, many months.

On May the 1st of this year IREP was updated to version 5.2.1. Each of the changes that I discuss today are extremely minor, which is the reason that we felt that a minor difference in the version number was warranted. This first slide that you'll see just briefly runs through the updates, then I have at least one slide prepared for each of these updates, so we'll get into more details. Back last October Russ Henshaw from NIOSH introduced to the Board this idea of the minimum latency adjustment functions for leukemia and for thyroid cancer. Then again in March he presented a more finalized approach at how this would be handled. These changes have now been implemented.

When entering the radon exposure information for someone exposed to radon, in the previous version there was a pull-down menu. It let the user select total or annual. Turns out total -- never used. We removed that pull-down menu to avoid confusion, doesn't make

any difference in the final outcome.
We've added some help. It's basically a link to tables that are already in the NIOSH-IREP technical documentation. We've provided links to those PDF versions that can be downloaded, and we've provided a help button that will give guidance when the dose is being entered on which radiation type to select.
Now all of these updates are discussed on the OCAS web site. There's a really detailed paragraph there that gives these details.
Now when I talk about latency here, I'm talking about the time between exposure and when the cancer was diagnosed. The previous version of NIOSH-IREP assumed a two-year minimum latency for leukemia and three years for thyroid cancer, and so the word minimum there is the key, because if an individual was exposed and then got leukemia within two years or thyroid cancer within three years, they were given a zero probability of causation. All other cancers in the model would at least give some small probability. There was no uncertainty assigned for that minimum latency period. It was two years and it was three years. The PC was

zero.
In the new model these revised latency adjustments now result in non-zero risk for all times since exposure, so even one year after, you're going to get a non-zero result. And this change also results in no decrease in probability of causation in any of the time since exposure compared to the previous version.
Okay, now we get into this radon exposure change. The pull-down menu that I mentioned in the previous version allowed you to enter it as total or annual. The revised version now just asks the user to enter everything on an annual basis. Just like entering dose information for an exposure, it's best to have it per year. The model can handle that much better, so this ensures that the latency period for lung cancer is properly accounted for -- and this kind of goes back to the previous slide. If someone got lung cancer two or three or four years after their exposure, entering their exposure information annually would allow the code to properly account for that, plus this simplifies the input screens for radon exposures.
Cancer model help, this is the help button right on the

primary input screen that gives guidance for the cancer -- cancer type, cancer model pull-down menu. There's a very full list of cancer models there to choose from, but it's not every single cancer type that's out there. And so the tables that NIOSH put together -- it's about six, seven, eight pages long that give all the cancers and then which cancer model in NIOSH-IREP to select. Once you click that help button right from the primary input screen, you can download the complete NIOSH-IREP technical documentation, as well as tables 4 and 7. Here's what it looks like, and the red circle indicates where the button has been added. When you click on that, it takes you to this screen. You can download table 4, which is the cancer models to be used, the primary cancer sites. If all you know is a secondary cancer site, table 7 is the place to go. Then you can click here to download the complete documentation.

We've added a help button also to give guidance on which radiation type to select. This would be alphas, electrons, those sorts of things. This has primarily been added for the general public that might access the

site and want to look through these sorts of things. Our dose reconstructors at ORAU are very knowledgeable on all these sorts of things and they know which one to select themselves, but this is a very well-written help file. David Kocher will go into some more details this afternoon about this one.

In that help file there there are important distinctions made between exposures that were internal and external exposures.

This is a screen shot of the previous version. The radiation type, pull-down menu that I am discussing was here (indicating). In the new version we just simply added a help button there (indicating).

So those are the four changes that we've made to update version 5.2.1. We're so excited you guys are here in our hometown and we've got four of our staff here to talk to you today.

Iulian, if you'll come ahead, we're ready to get into some details about our recommended updates.

DR. APOSTOAEI: Can you hear me? Yes. Thank you for introducing me, and I think you pronounced my name very, very well. That's one of the best pronunciations

I've ever heard around here. So I hope you can tolerate my accent, too, so...

Brian discussed about modifications that have already been implemented in IREP. I'm going to talk about some -- some updates that we here at SENES highly recommend to NIOSH and to the Advisory Board. We're going to talk about a couple of updates. The first one relates to bone cancer. Bone cancer and especially for the latency period for bone cancer.

At this point bone cancer has a latency period which is assigned the same value as for all solid tumors, which is about ten years. And it seems, based on more recent research that we did, that the latency should be lower than ten years -- an average of ten years, maybe about five years. And this change would be very claimant-friendly because it will produce risks at lower times, shorter times after exposure.

Another recommended update has to do with the application of the risk coefficients for thyroid cancer, and I'm going to discuss about this update in more detail.

As we speak, in IREP the thyroid risk coefficients for

exposure at ages less than 20 are reduced by a factor equal to the radiation effectiveness factor for X-ray -- X-rays. And this represents the state of knowledge that we had about a year or so ago when we first released IREP. And here is the rationale behind this reduction factor.

IREP uses a risk coefficient obtained from studies of individuals exposed to high energy gamma rays and was designed to make use of them. We have risk coefficients for individual exposed to high energy gamma rays for all cancers other than for thyroid. The risk coefficients for thyroid cancers are obtained from a pooled analysis of studies of children exposed to X-rays and also gamma rays, and also adults exposed to X-rays and gamma rays. It just turns out that the risk coefficients for children are dominated by the studies in which patients were exposed to X-rays, and adults -- the risk coefficients for adults are dominated by the gamma rays -- by the exposures to the gamma rays by the A-bomb survivor studies.

We believe that X-rays are more effective in inducing thyroid cancer than high energy gamma rays, and David

Kocher will talk about this a little bit later on, and I think you had a presentation on the effectiveness factors.

So of course if the risk coefficients for thyroid cancer for childhood exposure are dominated by X-rays and X-rays are more effective in inducing cancer, then we had to reduce them by a factor equal to their effectiveness factor.

However, we learned some more about the studies, these pooled analyses, and we learned that really there is no important difference between the risk coefficients from exposure to X-rays and the risk coefficients from exposure to high energy gamma rays. And let me show you a sample of the data.

Here this graph shows the risk coefficients for an exposure to radiation at exposure less than 15. The numbers in green here are the studies in which children were exposed to X-rays and the part in blue is the study for the A-bomb survivors. As you can see, if we look at the risk coefficients from the A-bomb survivors, the risk coefficient does not -- is not very different from the risk coefficient that would be

obtained when we pooled all this data together. So some of the risk coefficients from exposure to X-rays are lower, some of them are higher. When you mix them up, you will get a risk coefficient that is very close to the one obtained from gamma rays.

So a possible explanation for such an effect is that the X-ray exposures were applied to the patients in the fractionated mode, therefore induced a lower risk, in a similar way as a DDREF is applied.

So the conclusion is that the risk coefficients from the pooled analysis which comes from X-rays and gamma rays combined are consistent and that a good surrogate for the risk coefficient that we need would be those from exposure to high energy gamma rays.

So our recommendation is to update the application of risk coefficients for thyroid cancer by removing the reduction factor for exposure at ages less than 20.

Let me show you what kind of an effect this actual recommendation has. These are the risk coefficients, which are the excess relative risk per any dose for thyroid cancer as a function of age at exposure, and these are the values currently implemented in IREP.

And you can see a decrease in the risk with age at exposure with only one exception. Here there is an increase here at age 20 because these values have been artificially reduced and the data that we have on thyroid cancer indicated there risks should decrease continuously.

If we apply this update, the risk coefficients, now in blue, you will see that there will be no difference for exposures in adult. The risk coefficients for ages at exposure 50 and 20 will be increased and, you know, the data will now show -- the risk coefficients will show a continuous decrease with age at exposure.

Just a reminder, this update will affect only a small portion, will affect only categories -- exposure at ages 15 to 19, so it's probably a very small impact on the total number of claims. But nevertheless, this -- we believe that this proposed update is scientifically defensible. It's also claimant-friendly for age at exposure under 20. It increases the risk. And also will -- has already been approved by the National Cancer Institute and they already implemented in their version of IREP, which is the new version of the

radioepidemiological tables. So we believe that it's probably best to include these updates, even in the current -- in the new version of IREP and this is our recommendation if you want to consider it. Thank you very much. So let us know -- both of us --

DR. ZIEMER: Thank you. We'll open the floor for questions to either of the presenters, and I think in addition I might point out that two of the other SENES people are here. Owen Hoffman and David Kocher are also here with us today at -- I believe they're both still here, but let's address our questions to the two presenters here, if there are questions.

Okay, Dr. Roessler.

DR. ROESSLER: The -- one proposed update affects the ages under 20. How many people -- I mean that doesn't seem like it's really pertinent to this particular study. It may be pertinent in a big --

DR. APOSTOAEI: Yes, the cutoff for the claims is age 15, so --

DR. ROESSLER: But in reality, how many people actually would fall in that category?

DR. APOSTOAEI: Very few. Very few.

DR. ROESSLER: Yeah, I just wondered about that.

DR. ZIEMER: Thank you. Other questions? This Board gave a kind of approval to the previous update. We didn't think the previous one was overly significant, but we went on record as being in agreement with it. It's never quite clear where the line is between significant and a non-significant update. I'm not sure anybody knows exactly where that is. I believe that this is being presented to as a -- more of a tweak. In fact, it's -- shows, as the change in the number of the version, it's seen I think by the group as being not a significant update. It certainly is claimant-friendly. It affects, as Dr. Roessler suggested, very few potential claimants, but nonetheless the Board may want to be on record as to whether they are supportive of this proposed change, although it -- I don't believe it's required. Larry.

MR. ELLIOTT: NIOSH is taking this into consideration and we're talking with our colleagues at NCI about it. I would offer also that there are no claims relevant to this particular change, and we would -- if we thought it was something we'd like to see done, we'd

bring it to the Board for your --

DR. ZIEMER: So your staff is not --

MR. ELLIOTT: -- your deliberations.

DR. ZIEMER: -- yet at a point where you're making a recommendation --

MR. ELLIOTT: No.

DR. ZIEMER: -- to the Board.

MR. ELLIOTT: No, we're not.

DR. ZIEMER: So it would be premature I think then in that case for us to take any action today, but if you have questions, we certainly want to raise them. Dr. Melius.

DR. MELIUS: Can I ask Larry a question? I'm a little confused procedurally. What about the -- the bone cancer change, the -- or where do you -- where does NIOSH stand with --

MR. ELLIOTT: Well, we're -- we'd like to hear more about that ourselves. We'd like to know more about that. We -- I think the first I've heard about it was this morning.

DR. MELIUS: Okay.

MR. ELLIOTT: I don't know if Jim or others had heard

about the bone cancer modification, but we're in concert with NCI as much as possible and we're talking with Charles Land and others there about what -- what this would mean for the program.

Once we have one of these that we think we need to bring to the Board, we will. These were -- these things were for informational purposes to let you know that this is on -- on the horizon, and we need to get out thoughts collected and understand what they mean to the program.

DR. ZIEMER: Okay. Thank you. Other questions or comments? Tony and then Mark.

DR. ANDRADE: I'd be curious, perhaps you have a number at the top of your head, and if not, that's okay. If we can hear it later, that'd be nice. What were the sizes of the cohorts in the studies that produced these new results about the effectiveness, say for example, in the case of children, X-rays being just as effective as high energy gamma rays for production -- for the generation of cancer?

DR. APOSTOAEI: There are tens of thousands of children, including the exposures of children --

DR. ZIEMER: Is the mike on? I mean --

DR. APOSTOAEI: No, excuse me. Can you hear me?

DR. ZIEMER: Maybe just raise it up a little.

DR. APOSTOAEI: Yeah, so the studies that -- included exposures to X-ray by -- the children by X-rays contained thousands of -- and tens of thousands of children, and this is a much larger number than the number of children included in the A-bomb survivors. And for adults, we have only the A-bomb survivors, with very few exposures by adults to X-rays.

DR. ZIEMER: Mark?

MR. GRIFFON: I think you just answered my question. I was going to ask for a breakout of -- of the older age groups, what studies you relied on there, but I think also Larry answered that they're still reviewing this so --

DR. APOSTOAEI: The way the data is organized right now, I think exposures as an adults contain only exposures -- to the A-bomb survivors from Japan, so...

DR. ZIEMER: Okay. Thank you very much, gentlemen, for that input.

Just before we take a break I want to call attention to

the Board to the fact that tomorrow afternoon we will be dealing with some minutes. The tab near the back of your packet which is labeled draft minutes, meeting 11 -- that's the February meeting -- you are going to be receiving shortly -- this morning or early afternoon -- a substitute packet. This -- this early draft has subsequently been reviewed by the Chairman and marked up and there will be a new -- more concise draft, I'll call it and describe it that way -- which will replace this, which will require somewhat less reading for you tonight as you prepare for tomorrow's docket. But in any event, at that point you can -- well, you're certainly welcome to read through these minutes, as well. Maybe you'll like them better than the Chairman's version. But in any event, there will be an official draft that you'll receive sometime today. Cori will distribute it.

With that, let's take a 15-minute break.

(Whereupon, a recess was taken.)

THE UK COMPENSATION SCHEME

FOR RADIATION-LINKED DISEASES

DR. ZIEMER: We're pleased to have some special guests

with us today who are going to introduce us to the United Kingdom's Compensation Scheme for Radiation-Linked Diseases. That's the UKCSFRLD. That's what we would call it here, and I don't know how we would pronounce that. In any event, we're pleased -- and let me introduce briefly all three of the gentlemen who are here with us today.

Michael Lewis -- and when I give your name, just wave so everybody knows who is who -- or whom. Michael Lewis is a health physicist. He's had 18 years of experience with the -- in the United Kingdom in the nuclear industry there. Since March of 2001 he has been Executive Secretary of the United Kingdom compensation scheme, and in that role he's responsible for management and operation of the scheme. He's the only full-time officer of the compensation scheme, although he's able to call on numerous colleagues in the scheme's members for assistance in building case assessments.

And then John Billard is National Secretary with the Trade Union Prospect, which has 105,000 members, mainly in science and engineering in the United Kingdom. He's

been very active in promoting the compensation scheme for actually a little over a decade now.

And then Dr. Andy Slovak is the Chief Medical Officer -- British Nuclear Fuel, BNFL is -- I don't know if I'd want to call them the contractor, but they're the group responsible for handling this, and he's their chief medical officer and is responsible for development of standards and review of the company's Occupational Health Services, and then he has an oversight role in the medical aspects of radiation protection and radiation science, including epidemiology, radiobiology, genetics, and in these cases this extends to chairing the UK compensation scheme's Technical Working Party, as they call it. That's the body that's charged with tracking developments in the technical fields that are relevant to the scheme and recommending necessary changes.

So we're pleased to have all three of these gentlemen here. Let's see, we're going to begin with Mr. Lewis, and then Mr. Billard and then Dr. Slovak.

MR. LEWIS: Good morning, ladies and gentlemen. It's a pleasure to be here to be able to tell you something

about the UK Scheme, which is what we call it, rather than the UKCSRLD.

As you can imagine, we've observed the development and inception of your compensation program with a great deal of interest, not least because of the number of potential challenges it presents to the operation of our own scheme. I would also hope that this opportunity will give yourselves some chance to appreciate how another system works, and may even go as far as informing some of the decisions you have to make along the way.

What I'd like to do is tell you something about the background and history of our scheme, and explain something of how we process individual cases and how we manage the scheme between the effective owners, the unions and the various employers.

John will then tell you something of the union perspective of the scheme. Andy will, as the chairman of the scheme's Technical Working Party, will discuss some aspects of the technical basis that we use.

To understand why we have the scheme in the first place, it's perhaps necessary to understand the legal

situation in the UK. In the UK we have a thing called the Nuclear Installations Act, which requires that any site where nuclear operations occur needs to have a site license. And that Act also says any company that holds a license is responsible for the harm caused by those operations. There's no need under the Nuclear Installations Act to prove negligence, so simply by proving that any harm that you suffer has been caused by those nuclear operations would lead the employer to be liable, or at least the license -- the site license-holder to be liable.

And under that Act there were five trades-union-sponsored actions against BNFL in the late 1970's. The first thing to know is that they were very lengthy. It took around five years for them to get started and then to get to the steps of the court. They were very expensive. There aren't any official figures on how much, but between the employers and the unions we're talking well into -- you know, well over £1 million, UK money.

They were very traumatic for the families concerned because they were under immediate spotlight for five or

six years, as well as under a great deal of pressure in their own local community. And eventually they were settled out of court, which doesn't really mean that you've got the greatest success out of the legal system that's possible.

The reaction to this from BNFL and the unions was that there was a great deal of concern -- the distress caused to the claimants and the families, the duration and the actual financial cost to both parties. BNFL were concerned that it might actually be possible for a claimant to win such a claim. The unions were still concerned that it was very difficult to actually prove causation in a court.

And both wanted a workable alternative as a way forward, but it was clear that if there was going to be a workable alternative, it would have to be faster than the court process. It would have to cost both the employer and the unions a lot less money. It would need to be more generous to the claimants to give them an incentive to come to any alternative rather than going to court. And obviously it would need to be much less traumatic to those involved in making claims.

After a great deal of discussion between the two parties, the Compensation Scheme came into being at the end of 1982, initially for a trial period of five years, and the first claim was actually received in November, 1982. At that time the Scheme took mortality cases only, cases where the claimants had died of a radiation-linked disease. It was unique at the time in that it used the causation probability methodology, and that methodology was based on an excess absolute risk model which was derived from ICRP 26, which was -- at that time was felt to be the best scientific basis. After that initial period of operation, the Scheme was reviewed in 1966 (sic) and both parties felt that the operation had been successful and decided to carry on. At that time we also extended the Scheme to include morbidity cases, cases where the claimants were still alive, and the PC methodology was reviewed and generally supported by the publication of the NIH radioepidemiology tables over here in 1985 and the associated NRC review.

We did actually further revise the technical basis in 1991 following the publication of BEIR V, and that

remains the basis of our Scheme today.

The way we process cases is that every application has to pass a test of eligibility, and we then screen. If the screening test is passed, we then do a more detailed investigation, which is called a factual report. That's used to determine the case, and it then moves to payment, which, to use a -- we use the UK legal term, which is quantum. Quantum in the UK is the amount of money you pay in a settlement for an injury claim.

The eligibility criteria that we have under our Scheme is that claimants must have been employed by one of the Scheme participating employers, they must be a member or have been a member of one of the Scheme participating unions, and they must either have a radiation dose record with the employer or at least there must be sufficient evidence so we can infer an occupational radiation exposure history to allow us to causation probability calculation. And obviously they must have contracted or died from a disease that's covered by the Scheme. And if those cases -- if cases are eligible, we then move to screening.

The idea of screening is to identify potentially successful cases. We take the dose history which are collated and, in some cases, slightly enhanced by what we call protocols, which are agreed procedures for each of the employers who compile dose histories. In some cases we do use upper bound data in order to speed the process of the case through the screening period. We assign one of six schedules, which are our dose risk models, dependent on the ICD(8) coding of the disease that the claimant is diagnosed with, and that -- they are the basis that we use to make the causation probability calculation.

If the case produces a causation probability of less than 15 percent, it's deemed to have failed the screening process. I then inform the Union, and the Union informs the claimant and in almost all cases that's an end of the matter. If a case achieves a causation probability of 15 percent or greater, there is then a deeper investigation of the case done in terms of a factual report, and that factual report is then used as the basis for the final determination of the Scheme, which again is a causation probability

calculation.
Based on the causation probability that comes out of the factual report, we employ a system called proportional recovery. This means that if you achieve a causation probability between 20 and 30 percent, you will receive a quarter of quantum, which is the full sum payable. And then it goes on a sliding scale up to 50 percent, and 50 percent and over, claimants would receive the full sum of compensation, exactly as they would in UK law.
There were a small number of cases where special factors apply, where the Scheme schedules may be confused or confounded, and those cases are determined by what we call an expert panel. The types of cases the expert panel would look at are cases of leukemia where there is evidence of radiation exposure below the age of 21, respiratory cases with any evidence of a smoking history which achieve a causation probability of 15 percent or greater, and female breast cancer and thyroid cancer cases which achieve a causation probability of 15 percent or greater. And the panel determines a fractional payment in exactly the same way

as the payment schedule does.

Once a claim is awarded payment, it then moves to quantum. The idea of quantum is that the full sum is calculated in exactly the same way as a case would be if it was successful in a UK court. The employer and the Union both appoint solicitors at this point who are solicitors experienced in dealing with quantum matters, and they agree the full sum. The payment fraction is then applied and that determines the settlement that's given to the claimant.

We have a set of agreed time scales for trying to process cases. The principal time scale that we work to is the six months to issue screening data. That's the point at which the claimant would know whether they were going to receive payment or not. There's the opportunity at that point for claimants to challenge or to raise any concerns they have about their assessment, but the rule of thumb we work to is that within six months we try to let claimants know whether they are going to get something or not. And we achieve that in about 70 to 80 percent of cases, depending on the employer.

The Unions then have three months to respond to screening data if the case has failed, or one month if it passes. I mean obviously if it passes, there's probably a lot less dialogue to take place between the Union and the claimant.

The factual report is prepared within three months by the individual employer, agreed within one month by the Union, and then determined -- usually in a matter of days rather than a month -- once it is agreed. So the total target time scale is to run through the Scheme -- and if you like, all the I's dotted and all the T's crossed -- in nine months for failed cases and 12 months for cases which pass.

There is an alternative to the use of our Scheme. Again, our Scheme is not prescribed by legislation. It's a voluntary agreement between the employers and the Unions, so we can't make it compulsory and we don't seek to make it compulsory. Claimants can still take legal action under the Nuclear Installations Act, although the only thing we ask is if they are claiming under the Scheme, that they stay any legal action for the duration it takes us to assess that case under the

Scheme. And if an employer pays a settlement to a claimant, I think it's fairly common sense that the employer asks the claimant to sign that they will not pursue the employer under the Nuclear Installations Act for the compensation they've just been paid.

And one important feature is that the participants -- principally the employees and the Unions -- are bound by the principle of the Scheme. That means the workers have the security that the Scheme is available to them, with all its generosities over and above the UK legal process. And it also means that the employers are protected in some respects in that the -- in that Unions will not support cases through the courts where it is more appropriate for them to come through the Scheme.

If we look at the number of cases handled, I think if you compare these to the sorts of figures that David Sundin was talking about earlier, you can see that in one fell swoop last May we've gone from being a world leader to a drop in the ocean. In 20 years we've handled just about 1,100 cases. It's more a reflection of the size of our nuclear industry, I think, than any

personal inefficiency. Around 50 or 60 of those cases are currently ongoing, and in total 94 cases have resulted in payment. One of the important things to notice about those 94 is that 66 of those have been made at less than full payment, so if they'd have gone through the UK legal system and the UK legal system had adopted a similar assessment procedure to that we use, they wouldn't have achieved a payment in court, whereas we've given them compensation. And the total we've paid out so far -- again, you know, we're talking about drops in the ocean compared with you -- we've paid £5 million out so far, which is of the order of $8 million.

The way we manage the Scheme is that each employer or historical group of employers has a Compensation Scheme Management Board, and they manage issues pertaining to those particular employers, and there are five of those at the present time. I won't go through them, but there they are.

The way a Management Board operates is that it's established by the Unions and the employer signing a morbidity and mortality agreement, and they are pretty

much identical documents throughout the five Management Boards. The employer provides dosimetry protocols which are vetted by the Technical Working Party and endorsed by both employers and managers on the Management Board -- sorry, employers and Unions on the Management Board. And the Management Board has its own internal procedures for dealing with claims.

Management Boards nominate one management representative and two Union representatives to sit on the Scheme Council, which is the overarching management board of the Scheme, which makes sure that the Scheme operates consistently across the whole of the employer group. The Council meets once a year, and is actually chaired by the BNFL UK Management Board chair, and it's advised on technical matters by the Technical Working Party.

I also mentioned we have an expert panel who consider some of the more difficult -- technically difficult cases. The expert panel is a group of internationally-recognized independent scientists. The independence is important there. They are independent from the Scheme process otherwise, and from each of the employers and

Unions, so we are able to offer the comfort to claimants who are assessed by the panel that their deliberations will be out with any -- any interests of the participants. And at the moment they're averaging about one meeting a year. They usually consider two or -- two, three or four cases at their meetings.

We also have this body, the Technical Working Party, which I won't dwell on because Andy's going to speak about that. Andy, as BNFL Chief Medical Officer, chairs that body, and it exists to advise principally counsel, but also the management boards on technical matters.

The way that we usually demonstrate the success of our Scheme is the way that it's expanded from BNFL in 1982 throughout the UK nuclear industry. The United Kingdom Atomic Energy Authority joined in '87, Urenco* and the nuclear generators joined in '93, the Ministry of Defense and the atomic weapons establishment joined in '94, nuclear dockyards in '97, and a company called Babcock Naval Services -- who've just taken over running two of the nuclear submarine bases in Scotland -- are joining this year.

We've also expanded throughout the UK trades unions. Initially the Union members were those unions who represented the BNFL work force, and there were five of them. As the Scheme has extended through the other employers, the other trades unions who represent their work force have joined, and we now have all the unions in the UK nuclear industry represented, and they cover the majority of workers within the industry.

And I think that's probably the appropriate point at which I'll hand over to John, who will say something about the union perspective.

MR. BILLARD: Good morning. Can I say first of all I have to congratulate you on the work you're doing in relation to your compensation arrangements for radiation workers, and I'm pleased to say something about the trade union involvement in the Scheme, which Mike has so far explained.

And the first think I think is important for us is that the -- we have a collective agreement with the employers in the UK, which effectively means that the agreements are not legally enforceable, in common with all other collective agreements in the UK. This is --

our Scheme is an alternative to legal action, as Mike has explained. Therefore the agreement we have is known as -- it's "Binding in Honor" between the parties. It would, therefore -- there will be nothing to prevent any one of the parties walking away from it, but that would cause a number of industrial difficulties. And over the last 20 years I think we can truthfully say that all parties have worked together very well to make the Scheme the success it is.

The Scheme, as originally devised, was designed only for trade union members, and the reason for that of course is the nuclear industry in the UK -- highly regulated, highly organized, the great majority of workers in the UK nuclear industry aren't trade union members. So therefore it naturally fell to the trade unions to organize on their behalf in relation to the creation of the Scheme and its developments in 1992. Now as Mike has said, the alternative is a lengthy process, and we are there to give a service to our members. And it's absolutely essential that those who are taking part in the Scheme have whole and complete

confidence in what is being done on their behalf. We're there to present personal injury claims, if necessary. And as Mike has said, we wanted to avoid the lengthy and protracted and expensive process of legal action.

But the important thing is -- I'm sure you will have experienced this -- a worker is in the nuclear industry, experiences radiation during their working life, gets cancer and therefore of course there is a direct link which the claimant or the relatives seek to make, and therefore in order to persuade them or convince them in the event their claim is not successful -- and that's nine times out of ten, as far as our Scheme is concerned -- then those claimants have to be satisfied that the Scheme we're operating is operating under the latest scientific and medical knowledge. And that means that the members who are involved in claiming or their relatives or dependents would have to be able to go to them to say that we, on their behalf, have confidence in the outcome. And that same confidence has led employers to join the Scheme in the same way that Mike has described. And the history

of the UK nuclear industry is one of a public sector industry.

Nuclear research and development, nuclear in defense, has always been part of the UK public sector. But we've now moved to the stage where much of that is now operated by the private sector, and certainly the decommissioning task which is going to go on for another 50 or 80 years is going to be a private sector function and therefore we require those private sector employers to join the Scheme. And they have to have the same confidence that we do, because clearly if we're talking about private sector employers, we're talking about private sector money which may be paid in compensation.

Therefore one can see that the relationship between the parties in respect to trade unions, employers and the management of the Scheme is effectively a tripartite arrangement, and I've described it as a three-legged stool. If one is removed, then the thing collapses.

Trade unions and employers have good relationships and they have bad relationship. They are there to -- unions are there to represent their members. The

employers are there generally to represent their shareholders or their interest. And the employer/trade union relationship, going back well over 100 years, occasionally has its confrontational aspects. But I can say that as far as we're concerned in relation to the compensation Scheme, we operate a dance floor rather than a boxing ring. And we are there to work together for the good of claimants and indeed the good of employers.

Now nevertheless, in relation to the very interesting developments that we've been listening about and reading about in the US program, there are some issues for the workers, and that is why we are particularly interested in making this presentation and hearing what you have to say.

One of the things that immediately struck my attention was the concept of the Special Exposure Cohort, and I think when I first read details of the US program it was the SEC which stood out immediately. I think when I'd gotten beyond that and started to read and understand a little more about other aspects of your arrangements, it became clear to me you were very much

closer to what we have been trying to do over the last 20 years, but the Special Exposure Cohort of course cuts out a whole series of stages. In other words, you worked at Place A, you worked there for Time B, you got Cancer C, therefore you get money.

Now I have to say we've probably got quite a few thousand members in the UK who would like that Scheme, as well. Mike, for example, would probably be out of most of his job. I guess Andy wouldn't have a lot to do, either. But the difficulty is -- and I have to say that we do have a number of locations in the UK where radiation dose records haven't been kept as carefully as they should have been, and I'm talking about 20, 30 years ago; no doubt where practices were interesting, to say the least, and which have certainly changed as the industry has matured, and therefore there is an attraction. However, our judgment is, as trade unions, is that we would never be able to persuade any employer to join such an arrangement because they would see it as a liability -- a big liability, particularly -- particularly if you're dealing with the private sector, which we are, because there's no government money

directly -- no government money directly involved in the operation of this Scheme.

There are other interesting aspects of your scheme which I'm pleased to learn more about, and that is in relation to generosity factors. I know Andy will say something about that when he takes over from me shortly. I suppose if we take any one particular case, particularly one which might be on the -- right on the limit of where the compensation is paid or not, and we apply that case to your scheme, that individual may be successful under your scheme and not ours. But obviously that could equally work both ways. Our judgments are that, taken as a whole, generally the success rate of your scheme compared with ours, excepting the SEC, is broadly about the same.

So I conclude on those comments, ladies and gentlemen. It's been a pleasure to talk to you. And if you have any questions, I'll deal with those at the end, and I hand over to my colleague, Dr. Andy Slovak.

DR. SLOVAK: Thanks very much, John. I'm going to briefly run through -- review some of the technical issues in the Scheme. And particularly I'm going to

draw out some comparisons with your scheme and some rather particular features about where it's going.

I'll preface these remarks by saying that I had wonderful sense of familiarity with the delays and the frustrations and the irritations associated with the setup of your scheme. The running of it, I can assure you, will be just the same, and especially any challenges and adaptations in the future.

I was particularly taken also with the concept of pigs going down pythons, and I should add to that that greasing is sometimes difficult, and it doesn't get you past the pinch point.

Very briefly, you will see a series of resonances in what you're doing and what we've been doing for over 20 years, and the process of the Technical Working Party of which I chair is to make sure that all of these factors march in line with the advancement of science and understanding in these areas.

Our technical basis, as Mike has said, is based on BEIR V. We have a relatively simple set of schedules in comparison with yourselves, with many things tucked into something of a dust bit of other tissues, and

we're going to have an extremely fruitful time in the future, considering all of the issues associated with your -- your many schedules and our relatively few, and how that works for different people.

Here's the technical headlines of what we think are going to be some interesting areas and some possibly difficult areas of intercomparison between the US and the UK scheme. I've already highlighted the seven versus 34 dose models that you have, some of which I would say -- and perhaps slightly controversially -- may be straining scientific credulity a little.

There are a number of differences in the way that we approach dosimetry. We mainly use statutory dose records and some reconstruction. We don't make adjustments for the way the dosimetry was done for the geometry of the radiation nor the tissue attenuation.

And also we have this use of the 50 percent causation probability value, rather than the 99 percent confidence interval.

We also have some cancers which are quite specifically non-eligible. These are the ones that many of you who have a technical interest will recognize, and some of

them are arguable, and some of them no doubt will be argued in the future.

Like all good nuclear scientists, we can't actually leave well alone, so that we've taken BEIR and we've adjusted various aspects of it to make life easier for ourselves, and also to provide some level of in-built generosity to claimants. And I think one of the most interesting things I've already learned from this morning is that, similar to ourselves, there is a spirit here in this meeting of wishing to be generous and wishing to err on the side of benefitting claimants rather than taking some kind of narrow, legalistic sort of highly scientific point of view.

Now we come to what the Technical Working Party does. This is the dance floor, although I have to tell you that I don't dance so good, and many of the members would have some difficulty in doing it, but nevertheless, it is a scientific dance floor. Any party can raise an issue, a scientific issue, and this is done at a council or a board management level rather than a technical level, so we are told what to do by our political masters, if you wish. It is then down to

us to come back to them and say well, you know, this is how we see the problem. This is the technical scope of the problem, this is how far we're going to go. And they will say okay, that seems sensible. Or they will ask us to go 'round and think again. Once we get into the Technical Working Party, we tend to be very inclusive. Anyone can come along who is representing one of the parties to the discussion, and we'll listen to all inputs very carefully and factor those into the discussion. So it's very much a forum, and again, there is some resonances with one of the papers that we had just before the break of a free and open discussion of scientific issues and a consensual agreement to the approach then taken.

The next item here just shows some examples of issues that we've addressed over the last few years. Again, I keep on saying this, there will be all sorts of resonances of familiarity here -- non-uniform neutron dose; update of site histories, very important and not sometimes immediately obvious and has some kind of agreement -- agreed view of what happened on particular sites and when it happened and things like that, very

useful to the operation of the Scheme.
Quite clearly, you guys have come in like the whales and suddenly we're the minnows. You know, minnows get a little bit agitated when whales come along, so you know, we want to carefully watch what you're doing and very much interact with what you're doing for the future. Hopefully it'll be very much a bipartite approach, and one of the things that we've done which I think is perhaps an example of the sort of maturity of the Scheme is that we've begun to look ahead and say well, you know, what happens when you're going to start getting specific genomic proteomic* markers of radiation related disease, how that's going to affect the compensation scheme, are there going to be winners and losers. It may comfort you to know that our conclusion was well, it's much too early to decide.
So moving on now to what I think are the main horizon issues for us technically, we do think that there's going to be considerable benefit and value in having some kind of level of formal interchange at a scientific level with yourselves. We quite clearly have a set of resonances and sympathies in our attitude

and approach.
We are awaiting with great eagerness, as I suspect you are, the advent of the new, somewhat-delayed NIH tables, and any pressure you can bring to draw those forward would be greatly appreciated.
And another one which I think is going to get very difficult is non-cancer outcomes, which are beginning to come up in A-bomb survivors associated with radiation dose. Perhaps something not for the immediate future, but certainly just over the horizon.
Okay, so we conclude -- I guess we conclude on time. It's been argued to you, and I think the very fact that three of are wearing suits and ties can turn up in the same place at the same time, that the Scheme has demonstrated over 20-plus years that it enjoys continued support, not only from the employers and the unions, but also from the scientific community. This is supported by its extension throughout the UK nuclear sector. We are -- we note and obtain comfort from the fact that you're using the same basic methodology as we are in terms of causation probability. However, the DoE scheme does raise some issues for us in the UK.

Now I do know that that's a slightly challenging statement, particularly as we've left the word but we still have much in common there. We -- I'll repeat what I said a little bit earlier. We are very keen to maintain a functional scientific dialogue, particularly and importantly for the benefit of claimants to produce an outcome which is fast, caring and hassle-free. That's the end of what I have to say. We're very happy to take questions and I'm inviting my colleagues to rejoin me for that.

DR. ZIEMER: Thank you very much, and we'll begin questioning with Dr. Roessler.

DR. ROESSLER: I was going to ask Mike this question, and then John, but I think you're the right one to ask now, Andy, that you have talked a little bit more about the updating of science, or using the best science. And now that the new dosimetry is out from Hiroshima and Nagasaki, and now that it appears it won't take very long for it to continue on and get to -- so that BEIR VII will be able to finish up, I assume you have a team ready then to go to evaluate BEIR VII and be ready to make any adjustments, if necessary.

DR. SLOVAK: Well, we certainly have that very much in focus, and you know, the guy who's going to lead that is standing in front of you -- or would be if I wasn't actually retiring quite soon, so my successor will be doing it. But yeah, I mean we've been watching that one coming and we will undoubtedly need to have fairly extensive dialogue.

One of the things that we don't do is rush to judgment, particularly in a bipartite structure, it is necessary for the scientific impact of something as important as that to resonate 'round the scientific community and also 'round the trades union and employer communities for a little while before we draw all the strands in and come to some kind of view. I was also actually involved in the BEIR V reassessment, and that took about a year and a half to two years to settle down.

DR. ZIEMER: Wanda Munn.

MS. MUNN: I can't over-emphasize how marvelous it is to hear the experience from UK and see the similarities and be painfully aware of the differences in your situation and what we're dealing with here. I have some curiosity as to whether or not your experience

with your equivalent of our Department of Energy, which appears to be only about ten years in length as opposed to the entire Scheme, whether you have found that your experience with that particular work force is different than your experience with the broader commercial work force.

DR. SLOVAK: I'll turn to John to give the first answer to that. My views may be slightly more trenchant than his.

MR. BILLARD: Most of the workers in the UK nuclear industry once upon a time worked for the public sector, but we have had an extensive privatization program over the last ten, 15, now nearly 20 years. And it's been a matter for the unions to make sure that terms and conditions transfer, and therefore we primarily made it an objective for private sector employers coming into the industry that they would join the Scheme or be part of the Scheme. And I'm very pleased to say that so far, in respect of new employers coming into the industry, taking on existing workers, we have not yet had a refusal. And I think that is -- that is a credit to the way the Scheme operates, based on science, based

on knowledge.

I think there's a point you should note, and that is we never close a case. We might tell a claimant that they're unsuccessful, but their file doesn't go in the bin. In the event that there is a development in medical or scientific knowledge, the case would reopened if there's a chance of a settlement. All these factors lead to a confidence level which has meant that as far as the union side is concerned, there is no difference in approach between employers, whether they're in the public sector or the private sector, and we're very pleased about that.

DR. SLOVAK: Does that fully answer the question?

MS. MUNN: That's fine.

DR. ANDRADE: It was amusing to hear your remarks regarding our Special Exposure Cohort provisions, but I'm curious. Given the fact that you need to have bioassay or dosimetry records to follow up on a particular case for the Scheme, what would happen if, for example, there was a criticality event, there was no criticality dosimetry involved, but yet there were several witnesses to the -- to the fact?

MR. LEWIS: In that case we would look towards the employer's technical people to make some assessment of the potential doses to individuals involved in an incident like that. And that would be placed on record within the Scheme. Such a paper, and any paper that's produced regarding technical issues like that is, in the first place, discussed by the Technical Working Party, but it has to be endorsed by the appropriate Management Board. So whether it was to do with a criticality, whether it was to do with, for instance, an emission in the radiation monitoring regime over the years, it would effectiv-- within the Scheme be a transparent process and, you know, would require the endorsement of all parties.

That is one thing -- I think one thing we didn't mention in the presentations is that our Scheme runs by consensus. Within the individual meetings there's no vote and there's no bloc voting. Everything is agreed through the Chair by consensus by all parties. And certainly, given that my job is to run the Scheme independently and on behalf of the interested parties, it makes my job a lot easier that the decisions are

made that way. Is that -- is that okay?

DR. ANDRADE: Yes, thank you.

MR. GRIFFON: Along -- along a similar path as Tony's question, I'm just curious how your dose reconstruction process is similar or dissimilar to the one that we've outlined for this program and -- and along with that, I'm wondering if you involved -- you did any sort of interviewing of claimants and used that as part of your -- your registration efforts.

MR. LEWIS: No, we -- we don't interview claimants, except in the event that claimants raise certain specific issues, either at the outset of the claim or when the screening data is issued to them by the union. In which case we're talking -- out of 1,000 cases, we're talking less than a dozen cases where, you know, we have arranged meetings with the claimants, a union representative and technical representatives from the employers to discuss those concerns to identify whether in fact those concerns would lead to the assessment of doses additional to those already taken into account by the dose record. And if so, the employer's technical people would then -- as I mentioned to Antonio, the

employer's technical people would then do whatever dose reconstruction was necessary, and that would be channeled through the Technical Working Party and eventually agreed by both unions and employers and applied to the case.

MR. ELLIOTT: You used a term, Mike, that struck me as another difference between our two -- the Program and the Scheme, and that is transparency within the Scheme. Here in the States, our transparency is effected through these public meetings and the oversight, the consensus advice generated from this advisory body. Do you see that as being an issue as a difference between us, the Program and the Scheme?

MR. LEWIS: No, I think that's more of a cultural difference between the UK and the USA. I mean the way we consider democracy in the UK is that democracy is channeled into democratically-elected bodies or groups who then are empowered to act in whatever way they see fit under their (inaudible). And I think within the -- the way that works in the Scheme is that the union is a democratically-elected and constituted body and they represent the claimants who, you know, have a

democratic process within the unions, but the unions are the representatives within the Scheme.

Now whether it's because our scheme was conceived 20 years ago and 20 years ago you didn't have publicly-held meetings like this, I don't know. I mean whether that -- whether that is something that would change in the future, again, I don't know. But certainly for the moment, you know, we -- the -- all parties are represented, either through the employer representatives or the union representatives, and that's the way the democracy works within the Scheme.

DR. SLOVAK: Yeah, I'd like to just add something to that. We -- the Scheme is over 20 years old and it retains a high level of trust, and it sort of builds up its own steam of trust, if you like. One of the areas in which certainly the UK and much of Europe is lagging is in the provision of public information and public exposure of these issues to a broader set of constituencies.

Now under the Nuclear Installations Act, there are such bodies, and those issues can be raised in those bodies, and the nuclear ones are called Local Liaison

Committees. So you can have these discussions. By and large, our experience is that these issues have not been brought up, but I don't know whether that's an expression of confidence or whether they've got more important things to do. But we can do it, and so in fact there is actually not as much difference as you would think.

DR. ZIEMER: Thank you. Roy?

DR. DEHART: As an extension of that issue, has it been necessary for the Technical Working Party to use any external quality assurance measures or assessments?

DR. SLOVAK: We've never done so. We would be perfectly happy to do so, should either party take a view on any particular issue. I mean it's that flexible if either -- I mean our essential purpose is to obtain a consensual position. But if we had an area of disagreement or if there was a party which felt that it would be useful to do that, then we could accommodate that simply by saying well, that's what we're going to do from now on or that's what we're going to do for this particular issue because it seems desirable.

DR. ZIEMER: No further questions or comments? One more here.

MR. ELLIOTT: I'd just like to thank you all three for coming to the States and spending time with us this week. They will be in Cincinnati with us for the remainder of the week, and we'll be having some of these technical discussions, but we certainly appreciate your presence here today and your very valid comments to this Board. Thank you.

DR. ZIEMER: Yes, indeed, it's been very helpful. Is there -- the Department of Labor representative also has a comment here.

MR. HALLMARK: Sorry to drag this out, but since we have this opportunity, it's wonderful to hear and I second the thanks from the Board for your presentation to hear about people who've been doing this for 20 years as we struggle to get started. But I had a couple of questions I wanted to ask. One is, you mentioned the SEC and your not having an SEC, but you did have something called a Special Factors Panel, expert panel that you elaborated that addresses itself apparently to specifically difficult cases. And I

wondered since you had such a seemingly successful strategy for resolving disputes among the parties, why you would need this further group to resolve the really difficult disputes. That's one question.

DR. SLOVAK: All right. Well, we'll both try and answer that. The Expert Panel was set up at the inception of the Scheme, partly I think because of the reasons that have been expressed by several questioners about trustworthiness and reliability and external peer review. What has actually happened within the Scheme is that the role of the Expert Panel has actually been narrowed as we've gained experience with operating the program. It's still very useful to have them because we do get the occasional tough one, and it's a good idea -- maybe this is sort of the underlying purpose of your question, really, is it is useful to get a second opinion on some of these things. Also, because they're extremely distinguished scientists, they will raise issues and feed them back into us where they don't think that we're quite clear about we're doing. We've certainly brought things back into the technical structure in order to do that.

MR. LEWIS: Just to reiterate on what Andy was saying, really I think the Panel -- I personally would view as a representation of the strength of the Scheme rather than a weakness. We recognize that in constructing our schedules there are some small areas where particular features of particular cases might mean that the answer you would get from using the dose risk relationships presented by the schedules may not answer all questions for all cases. So the Panel really exists, in the way they work at the present time, to consider more deeply those cases where the schedules don't give you a particularly reliable answer for all sets of circumstances.

DR. ZIEMER: Did you have an additional question?

MR. HALLMARK: I had one last question, which is I heard I think Andy indicate that he had an assessment of the success rate being experienced so far, other than in the SEC, here in the United States. I'm not sure that that's really a mature number. And I guess this is more a comment than a question. I'm not sure you're able at this point to take -- make much of a sensible judgment about how the success will flow from

the NIOSH process, and I guess the question that's imbedded here is what impact will that have on the confidence issue you're raising in the UK if in fact the success rate is higher through the NIOSH process?

DR. SLOVAK: It was John actually who said that. And it was the state where I was going to nudge him a little bit and say well, that was very kind of him to say so and we'll watch your experience with some interest. I think that's the polite way of putting it. Quite clearly we would be quite concerned if large differences began to appear. It would put an enormous amount of pressure -- I suspect more on our trade unions than ourselves, which is why he's here and John may want to add to this -- to seek a review of the whole process. But, you know, we will see. And if there is any problem -- if in the intercomparisons there are problems, we will have to address them.

MR. BILLARD: I simply endorse those remarks. We've run our Scheme pretty successfully over the last 20 years, but we're certain to have things to learn in the future. And in the same way that science and medicine is developing in the treatment of cases, I think

jointly we're likely to experience such future changes, which I'm sure will be beneficial. But if -- if -- we have about a ten percent success rate, you see, and that's been pretty consistent over the past 20 years. And if you're coming -- if, as time goes by, you start to come up with something which is, you know, reasonably significantly different to that, we are not going to get science and medicine to defend us. We're going to have to start to get some political elements coming in, which we will have to deal with. But I think time will tell. But I think, having heard what we've heard so far about the US DoE program, we're reasonably confident that we won't have these difficulties, but we'll see.

MR. LEWIS: If I could just add one thing, I think it would also go to how the dose profile of your potential claimant population compares to ours. Certainly within our Scheme there are quite striking differences between each of the employers. For instance, if you compare some of the BNFL claimants who worked in some of the reprocessing buildings in the fifties, sixties and the early parts of the seventies, the sorts of doses

they've received over their working lifetime are vastly higher than somebody who spent 30 years working on an AGR power station. And whilst you could make the general comment about success rate, I think you would have to understand, you know, what the underlying dose profile you were dealing with between the two industries was. I mean I would guess that there would be areas where there's a great deal of comparison, but there may also be a few areas where you might have experienced a particularly high rate of claimant success where, you know, there may not be such striking comparisons with the UK nuclear industry.

DR. ZIEMER: Thank you very much. This has been very helpful and I'm sure we'll both be looking at each other as the years progress here, but we do, again, appreciate your time, sharing with us not only today but with the NIOSH staff the rest of the week, so thank you very much.

MR. LEWIS: You're welcome.

WORKING GROUP REPORT

DOSE RECONSTRUCTION REVIEW PROCESS

DR. ZIEMER: We're going to proceed to a report of the

dose reconstruction work group. Mark Griffon is going to give us that report. Also I'd point out that we have another part of our agenda devoted to this topic so that even though it may look like we're shortchanging it a little bit here, we do want to break at noon. But Mark, you understand that we do have additional time tomorrow so that if you're unable to complete all your -- in fact I think you probably will not complete everything 'cause you may have some additional things under preparation that will come to us tomorrow.

And Mark, if you would, when you begin your report, also include a brief summary of the meeting with the potential contractors that was held in Cincinnati in -- earlier this month, actually.

Board members, let me point out that you should have received recently in the mail a summary of the meeting of the work group in Cincinnati, a summary of that meeting with the potential contractors. What did we call that meeting, the --

MR. ELLIOTT: Pre-Bidder's Conference.

DR. ZIEMER: -- Pre-Bidder's Conference. If you did

not receive that summary, please let Cori know, but it was not exactly a set of minutes, but it was a summary of what was done.

And Mark, if you can recall also who attended that conference on behalf of the Board --

MR. GRIFFON: I will --

DR. ZIEMER: -- if you'll --

MR. GRIFFON: -- try, yeah --

DR. ZIEMER: -- share that, too.

MR. GRIFFON: -- if I miss someone, you can fill in. Let me just start -- this is a -- boy, I can't even see my own overheads. This is a -- I wanted to give a little background for those in the audience that haven't been following our working group work. This working group has been established to look at how the Board -- the Board's role in reviewing the dose reconstruction activities that NIOSH is conducting, and the Board is required by statute to review the scientific validity and quality of NIOSH -- of NIOSH's dose estimation and dose reconstruction efforts. And what -- so far our work -- where we've gone with this work is that we're going to look at individual dose

reconstruction reviews, we're going to look at site profile and worker profile reviews, petition -- Special Exposure Cohort petition reviews, as well as a review of the procedures used by the -- by NIOSH.

And to complete this effort, the Board has determined and NIOSH is helping to hire a contractor to assist the Board in doing these reviews. We -- the working group, along with the entire Board, assisted in the development of the actual task order contract, and it was recently published. NIOSH -- as Paul just indicated, NIOSH recently had a pre-bidder meeting where we entertained questions and the working group -- some of the working group members were present. Let me -- let me -- I -- Paul was there, myself, Tony Andrade, Rich Espinosa and -- was that it? I think -- and Bob, I'm sorry. Bob Presley was there, yeah. And we -- we entertained questions from potential bidders at that meeting. And I think where that stands, and I'll have a schedule at the end of this presentation, but the bids are due June 2nd, and we're hoping to get all this on line by this -- by the early September time frame of this year so that we can have a contractor in place

that will assist the Board in reviewing all this stuff and reviewing dose reconstructions. So that's just a little bit of background.

The working group, as a -- let's see, you can see -- you can see I'm very prepared for this. I can't see my own overheads so I don't know where I'm going with this presentation.

The working group's tasks -- let me just -- yeah, let me put that on.

(Pause)

How's that?

UNIDENTIFIED: That's good.

MR. GRIFFON: Is that all right?

UNIDENTIFIED: Yes.

MR. GRIFFON: All right. The working group tasks -- and some of these overheads will show up from last meeting's efforts, but I've filled in some gaps on them. We're -- are now in the process of looking at -- developing draft procedures for the review process, developing procedures for case selection, and develop the individual task orders. So we have the task order contract, and out of that we have to develop individual

task orders for certain tasks that we are going to ask the contractor to do.

As part of our effort, we went to ORAU. I did a little follow-up visit to NIOSH after the pre-bidder meeting where we looked at the database that NIOSH has set up, and we -- we just wanted to get a sense of what the files look like. What does a completed dose reconstruction look like, what does the administrative record look like, what kind of files can we expect to be in this review, what kind of records are in this review. We tried to walk through our draft procedures for the basic and the advanced review against some of the -- a couple of these example cases, these completed dose reconstructions.

We -- so far what we've done, we've developed the basic and advanced case reviews, and we focused on individual case report forms. We actually have drafted two of those. Since I was tardy in getting my handouts to the Committee, we don't have copies right now. But essentially these -- these forms sort of track the task orders themselves and look at the data-gathering elements, the interview process and the actual dose

estimation process, those three elements that are outlined in the task order contract which -- I don't know if we have handouts of that stuff here today, but -- which we've looked at before.

The summary report form, the difference here is that we -- we envision the contractor will assist in -- or will write up a report for each individual review, but also will write a summary of a group of cases that they might have done, and that will be a presentation. So that'll be more of an executive summary type of format where they look at sort of aggregate findings from a group of cases, and that's the sort of presentation we envision back to the Board to all Board members.

On this first part, the individual case review, we -- in the working group we keep reminding ourselves that this whole process is the responsibility of the Board. And we have talked about before, and I'll bring it up again, the fact that the Board members will be involved with the contractor. And we've envisioned different schemes on this which I think we have to nail down fairly shortly, hopefully at this meeting, of how the Board members might rotate in and work with contractor

staff. So you might have a group of ten cases and two Board members are assigned to work with the contractor for those ten cases, so they would -- they would get -- those two Board members would be more engaged on the details of that review. The rest of the Board would certainly get the sort of executive summary of those reviews but wouldn't have to be involved in -- in all the details of those cases, sort of -- that's partially an attempt to space the work out, but also partially an attempt to make sure the Board is not just totally relying on the contractor but is involved in the process, as well.

The last item is the Board report form, which would be the report that the Board would then forward to Health and Human Services.

This -- as we did -- as we drafted these procedures, one thing that strikes me in this review is the -- as I said, they're direct from the task -- task order contracts, and if you have that language in front you, you'll notice that some elements are fairly subjective, such as the one I noted here, that -- this is -- is much -- a lot of judgment or subjective input has to be

given consideration in this review. Other items are very prescriptive, you know. We -- I think we have one item that says did NIOSH receive all the data requested from DOE. Well, that's a fairly prescriptive element. But there's others that are fairly subjective and are going to require a lot more input and elaboration probably by the contractor in the report. It won't just be a simple yes or no response to some of these items.

We also -- another thing that came from the discussions on these two report forms was the question of the individual case versus the summary findings. And I think we talked about the prim-- one primary purpose of this effort is to get a sense, program-wide, if there's -- if there's problems that are leading to across-the-board problems in the program, if we can get a sense of that in the summary findings more. But I think we also have a question of if an individual case -- if the contractor -- actually the Board makes a determination that there was some errors in the case that would result in a change in the outcome, it might push it over the 50 percentile mark, then we have -- that's a

question we have. You know, what if -- what if we run into those kind of situations, what -- how do we -- what recommendations do we make to NIOSH, how do we handle that procedurally. So those -- those issues came up when we were walking these through.

Then -- this is another thing, and I -- this morning our working group just met real quickly to go over some of these things, and I -- I don't know why I did this, but I volunteered us for a couple of things in the next two days which I think we can really hammer out while we're all here. One of them is this process, so I'll volunteer the working group to take a stab at a first draft of this. We -- and certainly this afternoon we can discuss it more to get it all out on the table. The process of how, you know, when we -- we select a case, the case then -- well, even to the point of, you know, the administrative record is put on a CD maybe for distribution to the contractor. Can the -- can the Board members also get that CD. There's some Privacy Act questions there.

Once the contractor reviews, then how do we assign Board members to work with the contractors on certain

cases, when do we meet -- how do we coordinate the meetings. We talked about coordinating them such that they could be held prior to Board -- prior to Board meetings so we wouldn't have to travel too frequently. And then right down to the presentation of the final report from the designated Board members with the contractor back to the full Board, how would that be handled. So we -- we want to -- to sort of spell that out in a procedure format and then have a draft for the Board so that we can sort of tear it apart and mark it up and make -- make something that's going to be workable for all of us. So that is -- that is hopefully on our agenda for tonight.

The case selection process -- this is one thing that -- that we did work on at NIOSH by -- by looking the database and with some help from Dick Toohey, who actually gave me some statistical data on -- at least as it exists on the day we were out there, some 12,800 cases I think were there. We -- we got a sense of a cross-section of cases by site, by other demographics. And we -- previously we've talked about the 2. -- sampling approximately 2.5 percent of all the cases and

establishing a matrix of the selection criteria so that we would sort of do it and -- we're not completely -- I'm not completely sure in my mind how this is going to work because the number of com-- we're only going to look at reviewing completed cases, so the number of completed cases keeps growing, so I'm not sure how we're sampling that pool to fill in our matrix as the -- as the sample pool is growing. But we can -- we can work that out, I'm sure.

But the idea then is to -- based on the cases sampled -- fit them into a matrix of parameters that we've outlined, and I have those on another spreadsheet if you want to pull those up, some that the working group has considered, at least.

This is probably very hard to see in the back, I'm sure. Can you slide it over, Jim? Sorry. There, just slide over to field A, yeah. Right over here where you were.

(Pause)

DR. ZIEMER: Just go to the right a little bit -- there.

MR. GRIFFON: There. Not a big fan of Excel, huh? No.

The tracking -- I just labeled this tracking ma-- this is very draft, very preliminary, but we -- we had some -- some data that we thought was worth using. The site group on the left-hand side and I put site/group. If you'll notice on the -- we sorted -- I had a -- a sort of these by the number of claims, again, a snapshot in time. And the highest to lowest basically is on the left-hand side. That count, if you look, is actually the number of claims times 2.5 percent, so that'll give the number that we would sample. You know, that we want to meet -- that we want to get out of Savannah River site.

As we go down, on the bottom -- the very bottom of number 29 you can see industry groups. The question is, when you get to a point where you have less than -- the number of claims at an individual site are less than one percent or -- say one percent of the entire claims available, you really can't sample two or three percent of that, you know, group. It -- there's not many cases there to sample. So we thought about grouping those and hopefully -- with NIOSH's help, grouping those by like industries. I think there's

several of those AEC sites that can probably be grouped by similar types of industries -- uranium processing or that sort of thing. So then from those industry groups, we would sample a total number of 47 out of those -- all those other groups --

DR. ZIEMER: Mark, clarify column E, what is column E?

MR. GRIFFON: Column E -- okay, column E -- all right, so -- so over here -- there's -- there's several different criteria here that -- we've got -- different parameters that we want to fill this matrix in on. One is the site, right, or location. The other is cancer -- cancer type, and cancer type, this is a percentage of --

DR. ZIEMER: Well, take oral cavity and pharynx, that --

MR. GRIFFON: Right, if you --

DR. ZIEMER: Go back to column B. Does that say there were 37 of those at the Savannah River site?

MR. GRIFFON: No, it says that there were -- there were -- 2.4 percent of all -- of the overall cases or eight would be the number we'd want to sample.

DR. ZIEMER: Oh. What is the 37?

MR. GRIFFON: Thirty-seven, they -- there -- there's sort of -- I didn't put divid-- fancy dividers, but this goes with this parameter and this next two are with cancer.

DR. ZIEMER: Oh, I --

MR. GRIFFON: I should have -- I should have --

DR. ZIEMER: So 37 SRS cases --

MR. GRIFFON: Right.

DR. ZIEMER: Okay, I'm -- those don't go together then.

MR. GRIFFON: We can format this a little better, yeah.

DR. ZIEMER: Gotcha, gotcha, okay.

MR. GRIFFON: It's in very raw, user form here. So the parameters mainly to look at are the site, the cancer type, job group, the decade first employed, and you'll notice on the decade first employed -- or maybe you won't notice -- the decade first employed, we had forties, fifties, sixties, seventies, eighties. We certainly weighted the sampling -- or we propose weighting the sampling of that toward the earlier years because we think that's -- that's when more of the -- more of the issues as far as dose reconstruction would be found.

Then the primary radiation type, you have external, gamma, neutron, beta and also internal, and I just listed some I -- this is not sup-- intended to be extensive at this point, but I think we -- the notion is that we'd want to at least see some cases where you did plutonium reconstructions, some internal dose plutonium reconstructions, obviously. That's an easy one. But how many and the breakout of that, I don't have right now.

The final column, which you can't quite see, is the outcome. Outcome is, you know, either approved or denied, and we talked about weighting the sampling of those by less of the approved cases to be reviewed and more -- you know, more weighted toward the denied cases, 80 percent on the denied side. So again, the idea is that you sample randomly from an existing pool and say I pull out a case and it's a Savannah River case, it -- it's a supervisor first employed in the fifties, a primary exposure was of plutonium and it was a denied case, so you sort of fill in your checks as you go along and until we meet these numbers, basically, and that's the sort of initial proposal of

how we will work this tracking.
There may be some parameters that -- we had a laundry list of parameters I think that we started with. These are the primary ones I think that kept coming up. Certainly if I missed something, that's something for dialogue. But that's where we are on that and --

(Pause)

The other element which I volunteered my -- my team members for this morning was that we want to develop the task orders, and -- and we -- we feel this -- we wanted to have these in the hopper by the time the contract is awar-- contract or contracts, I should say, are awarded in early September. We want to have these task orders ready to say okay, here, you know, give us an estimate on these and let's get the ball rolling. So the idea -- we think fairly easily that we can at least get a draft of a basic review, advanced review and a procedures review because after eight versions of the primary contract and going through all that language many times, I think we've -- we've got some -- some language that we're all pretty happy with, and it's fairly specific so we think we can pull a lot of

that from those sections of the original task order contract to develop these task orders. And we're going to try to draft some of that this evening, too.

The only question I -- or request I would have is from -- laughing at me. The only question I would have from NIOSH on that is -- is if we need certain formatting for those contracts, we'd look to assistance from them on that.

And then -- then we have some discussion items that have come up through our -- our meetings in Oak Ridge, through our various discussions on these procedures, and I think these would be good items for this afternoon's agenda when we have further discussions on this. One -- one question is the Board and contractor access to data, and when I say that, I mean to NIOSH data and also to other records or reports which may be DOE or AEC records. The question I brought up earlier about the NIOSH data was -- Larry can probably expand on this a little more, but there is a question of how we -- how we are going to be able to deliver the administrative record for a certain case file to either the contractor or -- or I guess more problematic might

be the Board members that are involved in that review. Also the question there, which I don't think any of these are unworkable, but the question -- other questions are the site profiles or worker profiles. If the contractor's working remotely, they won't be on line on NIOSH's system where they can quickly go to all those documents, so how are we going to -- if they need these other documents -- or procedures or tech basis documents -- how are they to be provided.

And then on the bottom, the Board and -- and/or contractor access to site personnel and/or NIOSH/ORAU staff. I think there might be instances where the review contractor, along with Board members, may want to turn to a technical expert, a health physicist from the particular site or a retired health physicist from a particular site that might have even been noted in the administrative record. We just question whether that can be done or how that can be done, whether that has to be done through NIOSH to that individual or -- you know, how that might work was another question that came up.

A couple more items. Also a big issue that we've -- we

batted around earlier in developing this task order contract was the Board and contractor access to claimants for follow-up, and whether we can -- whether we can basically re-interview or -- or follow up on their interview. There -- as we know, there are no transcripts from these interviews so there's no record there to review. We did table this issue so that we could get the contract out, but I think we as a Board have to take that up again and see if we -- where we want to go with that.

And then I think I already -- I already said a piece on this, the individual versus the summary reviews and the question of whether it would change an outcome.

And I think -- yeah, the last thing is the schedule, and if I got any of this wrong, Larry, you -- or Jim, you can correct me. We did have the bidder meeting on April 30th. Work group completes draft task orders -- you notice there's no date there yet; we're working on it. Final proposals due June 2nd, and then there's going to be a technical review which should be completed by the end of June, contract award early July and task orders awarded by early September. Is that

accurate? So that's what we're pushing for and that's part of the reason we want to push to develop these task orders soon and maybe get a draft here so that we can get a final one at our next Board meeting.

DR. ZIEMER: This is a good point now to -- to recess. We will pick up discussion on this and have a chance for additional questions after lunch, about mid-afternoon.

Some information relating to lunch, Cori has menus from various eating establishments in the area. I think also -- at least I have -- I guess I got here a menu from this hotel, but all of these things -- Cori, are they back there? I believe there's a lot of eating places around close by.

MS. HOMER: The only information I have is from this hotel.

DR. ZIEMER: Oh, we have information only from this hotel. Okay, but there are other eating establishments around the area.

So we're recessed until 1:30.

(Whereupon, a luncheon recess was taken.)

AFTERNOON SESSION

AWARD PRESENTATION

DR. ZIEMER: Before we begin the formal afternoon session, we have a pleasant task to perform. One of the original members of this Board, Sally Gadola, who is an Oak Ridge person, lives here in Oak Ridge, works here in Oak Ridge but who's no longer on the Board, but is here visiting with us today. We're pleased to have Sally back here, and Sally, if you would please come forward and I'm going to call on John Howard, the Director of NIOSH, and on Larry Elliott, who's Executive Secretary of our Board, to make a formal recognition for you and to recognize that year or so that you shared with us on this Board. We're very pleased that we can do this today. We do all thank you for the time that you've shared with us. So here's a formal presentation. John.

MR. HOWARD: At last, a job that I have here. On behalf of the Department of Health and Human Services and Centers for Disease Control and Prevention, I want to award you a certificate for your service, and I'd

like to read it to everyone.

This certificate is presented in recognition and appreciation for service on the Advisory Board on Radiation and Worker Health of the Centers for Disease Control and Prevention as a member, signed Julie Louise Gerberding.

So it's my pleasure to present this to you.

MS. GADOLA: Thank you very much.

(Applause)

MS. GADOLA: It has really been a great honor and a privilege to serve on this Board, this very distinguished Board. I've met some terrific people. The expertise here is just overwhelming, but especially I am touched by the workers and their families and those that have spoken to us, and it just keeps reminding us what an important job this is. And I know how hard NIOSH has fought to make this as fair as possible. And I would just encourage all of you to continue your hard work, and thank you again for letting me serve you.

(Applause)

FUTURE CONSIDERATION OF UNCERTAINTY IN IREP

DR. ZIEMER: We'll return now to the regular agenda. We're pleased to continue with some information on IREP, particularly focusing on uncertainty issues, and then a little refresher on IREP, so we have with us Owen Hoffman. Dr. Hoffman's been with us before. We're glad to have him back with us again, and Owen is going to kick it off with this discussion on uncertainty in IREP.

Let me just mention, and I realize now -- I didn't know this morning -- that many of these biographical sketches are on the table back there, but I'll give a couple of abbreviated sentences, Owen, to save you as much time as possible.

But Dr. Hoffman basically got his doctorate in ecology at the University of Tennessee, and he currently is president and director of SENES Oak Ridge, Incorporated, Center for Risk Analysis. Dr. Hoffman's had several decades of experience in evaluation of risks to humans from the release and transport of toxic materials, particularly chemicals, radionuclides in terrestrial and aquatic systems. So he's also active in many professional areas. He's a member of the

National Council on Radiation Protection and Measurements, the so-called NCRP, and he's also a corresponding member of the International Commission on Radiological Protection. Owen, we're pleased to have you back with us today.

DR. HOFFMAN: And I'm pleased to be here in front of you and also would like to personally welcome you to our hometown of Oak Ridge.

The topic is future considerations of uncertainty in IREP, and for those of you out there that don't know what IREP means, it's the Interactive RadioEpidemiological Program, actually developed right here in Oak Ridge. And when you go on line to test drive it, it's actually being driven from servers within our Oak Ridge office.

The methodology used to quantify uncertainty in IREP is -- maybe I'll try this thing 'cause I don't like the sound of my voice coming in and out. Is this on now? Yes.

The methodology in IREP was actually derived from the same methodology that we employed from 1965 -- from 1995 to 1998 in the Oak Ridge dose reconstruction. So

for those of you who followed the work that we did here in the Oak Ridge health studies, it's the basic methodology that's now being used in the Interactive RadioEpidemiological Program. And one major area where this program differs from the scheme being applied in Great Britain is full -- the full disclosure of uncertainty in a quantitative manner.

Now the uncertainty in IREP is meant to reflect our current state of knowledge. That means when knowledge improves, the uncertainty should be updated. What I'm going to present here are areas where I feel IREP might be updated in the near future.

In one case, I will point to an area -- namely lung cancer and cigarette smoking -- where there are active efforts by the National Cancer Institute to update it based on new information that has come in from the follow-up of the Japanese cohort.

Now the prime envisioned updates of course will be the revised risk coefficients from the Japanese survivors.

As Gen mentioned, the dosimetry has now been officially revised. The cancer data will shift from an emphasis on mortality to an emphasis on incidence. We

would expect new data to emerge now within the next one to two years, especially with the ongoing efforts within BEIR VII of the National Academy of Sciences. I would expect also improved statistical methods of dose response analysis to occur, maybe even some Baysian* approaches, that would take information about those organ sites for which we have lots of information and applying that as a prior distribution to those organ sites for which little information is needed. Now within the worker community there has been concern expressed that the sole basis for the risk estimates, with the possible exception of radon and lung cancer and radiation and thyroid cancer, the sole basis of risk estimates has come from the Japanese cohort. But yet there's many studies on worker cohorts that aren't included in the IREP program. Perhaps in the near future there may be some efforts that are undertaken to combine datasets. I'm not saying replace the Japanese survivor data with worker cohort data, but complement the Japanese survivors data with worker data, perhaps even giving subjective weights based on the strengths and limitations of each of the studies. This could

occur.

Another area where I envision updates in the state of knowledge to modify the uncertainty estimates in IREP would be a re-evaluation of the assumptions used in transferring risk between the Japanese cohort and your U.S. populations. And the primary reason for this re-evaluation is to look at the sensitivity of risk to differences in the baseline cancer rates. And to what extent these baseline cancer rates differ among workers than among the general U.S. population, to what extent the models used for transferring from one population to another, are more likely to be either additive or multiplicative rather than some hybrid.

Currently, with the exception of stomach and breast cancer, we assume a lack of knowledge distribution that spans the entire spectrum between sub-additive and super-multiplicative, with very little weight given to the possibility of strict additivity or multiplicative relationship in the transfer from Japanese to the U.S. population. I think a re-evaluation might conclude that increased weights to either extremes might be justified.

Now this slide I want to pass through, but I was told we couldn't have hidden slides in the presentation, but I'm going to effectively hide this slide because that has been put into the presentation primarily to explain additivity and multiplicative transfer models for those who ask the question, but if you don't ask the question, we don't need to discuss it. It's in your handouts, however.

An area where I know that Richard Miller is especially interested in changing assumptions within IREP has to do with the assumption on the low dose and dose rate effectiveness factor whereby standard assumptions are that the risk due to chronic exposure to radiation at low doses will be lower than the risks observed when a cohort has been exposed at high doses to an acute exposure situation. However, I think that recent data on cohorts exposed to fractionated and chronic external radiation and chronic exposure to internal emitters may substantially update our current knowledge.

Now because of uncertainties in epidemiology and uncertainties in dose reconstruction for those cohorts, I think the distinctions that are within a factor of

two is going to be difficult to make, and therefore to say that the low dose and dose rate factor is indeed one or two, that's going to be different -- difficult to make, but I think new mechanistic information from recent low dose investigations with cellular and complex biological systems might add some light to the interpretation of these new epidemiological datasets. What do I anticipate? Well, I anticipate that there may be a reduction in the overall uncertainty distribution that we currently have in IREP for the low dose and dose rate effectiveness factor, and a possible decrease in the central estimate, whereby every decrease in the central estimate would bring about an increased risk, and every increase in the risk per unit dose would bring about an increase in the probability of causation.

The next two slides are just there as examples to show you the types of distributions for solid tumors, except breast and thyroid cancer, and for -- the distribution for breast and thyroid cancer currently in IREP. And what I -- I'm away from the mike now, but basically what I envision is some of the weight given to factors

down in this range may go down, some of the weight given to factors in this range may go up (indicating). Based on a re-evaluation of additional information sets than we had available to us at the time, we put the present version of IREP into place.

Now there's one area that I mentioned where there's action underway already, right now, by the National Cancer Institute to update what's in IREP, and this deals with this -- the interrelationship between lung cancer, radiation and smoking. The impetus for this revision has come from a recent paper published this year by Don Pierce and his colleagues at the Radiation Research Foundation and the publication is in -- I believe it's the March issue of 2003 in *Radiation Research*. This paper indicates that the interaction between radiation and smoking is most likely additive, meaning that the probability of causation at the same dose for a smoker will go down and the probability of causation at the same dose for a non-smoker will go up from what's in IREP.

There's less evidence for synergism between heavy smoking and external radiation. What this means is you

look at the risk from radiation, it's simply added to the risk from smoking, without there being a strong interaction effect. At least that seems to be the case for moderate and heavy smokers and somewhat arguable for light smokers.

In the present version of IREP we have a very strong difference between males and females. The new paper suggests that this difference is small and in fact is statistically insignificant.

In the current version of IREP there is no association with age, either age at time of exposure or the age at which the disease is diagnosed. The new paper by Pierce suggests a very strong age at time of diagnosis effect, and in fact this effect seems to be consistent with what has been observed for other solid tumors within the Japanese cohort. The paper includes a caution, however, not to extrapolate the results of this paper to the current assumptions to radon exposure and lung cancer because the mechanisms of action of small particles of the decay products of radon depositing in the upper regions of the lung and full uniform exposure to external radiation, these

mechanisms are inherently different.
Looking at this paper, I have come up with some preliminary -- well, preliminary -- let me call them not results, but preliminary implications of what appears to be the overall effect, assuming that the results from the Pierce paper are a more close -- a more accurate representation of our current state of knowledge. The implications to the current values in IREP are as follows: the IREP estimates of probability of causation are potentially underestimated for males whose lung cancers were diagnosed before age of 50, regardless of smoking history, and for females who were light smokers. Probability of causation would be underestimated for males who were light smokers and their diseases were diagnosed between the age 60 and 70.
On the other hand, the IREP values of probability of causation are potentially overestimated for non-smokers who were diagnosed with lung cancer over the age of 50, for moderate to heavy smokers with lung cancer diagnosed after the age of 50, and for females who were heavy smokers. And I'll show you some direct examples

of that, and these examples are also in your handouts. The examples I'm going to show you are derived from the estimates published by Pierce that are modified for the effect of age at the time of diagnosis of disease, smoking history and gender effects. And they're going to be compared with the values that are in NIOSH-IREP derived directly from the Japanese survivors prior to being adjusted for transfer to the U.S. population, and uncorrected and biased due to errors in the Japanese dosimetry. Now the reason for this is to make the two values as closely comparable as is possible. So for those of you who have copies of the Pierce paper, you will see that the values on this slide are identical to the values in the paper, with just a couple of exceptions.

The first is that the scale is logarithmic so that we can see clearly what is happening with the smoking effect. The confidence intervals have been increased from one standard error to two standard errors, so that we have a good representation of a 95 percent confidence interval. In the following estimates these values will be modified to account for the age at time

of diagnosis -- and let me just say, this is a big effect, whereby early ages at time of diagnosis, such as the age under 40, could be as much as six to seven times higher than the risk associated with ages over 60 -- and in gender. Now gender in this case is a small effect. It's about a factor of 1.3 upwards for females, a factor of 1.3 downwards for males. And then we will compare it with the values currently in NIOSH-IREP.

So for example, the next slide shows the values for a non-smoker male, these are males who have not smoked. These are the values from Pierce, and so it shows a strong age at diagnosis of disease effect whereby the highest risks are for the youngest ages and the lowest risks are for ages over 50, with the lowest being even over 70.

Let's look at how NIOSH-IREP compares to this. Now it takes your eyes a little bit to get adjusted to these figures, but here's what you look for. If the confidence bounds from Pierce go above the bands from NIOSH-IREP, there is a chance then for NIOSH-IREP to underestimate the results from Pierce. If the

confidence bounds from Pierce go below these bands, then there is a chance for overestimation. So in this case we have some chance of underestimation for the early ages at time of diagnosis of disease for non-smoking males, but a substantial chance for overestimation at later ages.

And we'll go through each of the categories now for the subsequent slides. For light males, we've seen -- for light-smoking males, we see strong evidence for potential underestimation of risk when lung cancers are ascertained before the age of 50.

Next slide. For moderate smokers, there is a modest chance for overestimation for the early ages at onset of disease -- for underestimation in this area and for overestimation for the older ages at onset of disease.

Next slide. For heavy smokers it's the same pattern. And if you were to look at NIOSH-IREP you would find is that the distinctions between moderate and heavy smoking -- in fact, even light, moderate and heavy smoking, the distinctions are minuscule in IREP. We include those categories, but when you analyze the differences in results, one would wonder why we even

bothered making the distinctions.
The distinctions are much larger in the new data from Pierce. So here for heavy smokers we can see substantial overestimation by NIOSH-IREP in the older ages at time of ascertainment of disease, and a slight chance for underestimation at the youngest ages of ascertainment.
For females, in IREP, as I mentioned, we have very large differences in risk as a function of gender. This difference diminishes in the data by Pierce. For females you'll see a large chance for overestimating risk at older ages at time of diagnosis of disease for females who didn't smoke.
Because of the way the multiplicative and additive model interacts within IREP, the uncertainty in the risk coefficients for the light-smoking female are actually suppressed, but giving rise then to substantial overestimation for the risks given for those who have disease at older ages and substantial underestimation for younger ages at time of ascertainment of disease. A strong effect of overestimation for the older ages at time of

ascertainment for moderate smoking females, and for heavy smoking females the same effect, just slightly more enhanced in the direction of the overestimation of risk. And in this case it even includes overestimation of the younger ages at the time of ascertainment of disease.

Now this is a comparison between the data in the Pierce study and the data now used in IREP. And the indications are yes, indeed, there is an opportunity to make adjustments, and I just would like to report that Charles Land is in communication with Don Pierce at RERF and he is -- well, in fact, he's made the decision to hold up the publication of the NIH version of IREP code until these updates are included. The updates may or may not be consistent with the differences that I've just shown you because there are many other considerations that Charles is taking into account. And in fact it does appear that he may even include an age at time of exposure effect in addition to the age at time of ascertainment.

Okay, that's one of the big areas where there could be updates. What are some others? Well, radiation

effectiveness factor is certainly an area where additional information could lead to enhancing our state of knowledge, and that could lead to an update. But that's the subject the David Kocher is going to talk about after I'm finished here, so I'll let David talk about that.

But by way of introduction, I want to alert you to our own concerns about the weight of evidence for the effectiveness of X-rays versus that of high energy gammas.

Now what's the overall effect of future updates into NIOSH-IREP? Well, as has been discussed many times amongst yourselves and amongst us, placing a decision criterion for eligibility of compensation claims at the upper 99th percentile of the probability of causation rewards for uncertainty. And if improved state of knowledge decreases the uncertainty but has no effect on the central estimate, fewer claims would be rewarded -- or awarded, and therefore there is disincentive then to engage in updating the IREP code to reflect an improved state of knowledge, and this is unfortunate. However, in updating our state of knowledge, additional

claims may become eligible if the central value of risk increases as a result of modifications, or if the upper range of uncertainty increases, and this would occur -- well, I would expect that to occur if we were to allow other cohort datasets to be used to complement the Japanese survivors in quantifying the original epidemiological data for excess relative risk.

The problems occur when the -- when no change occurs in the central estimate of risk, but uncertainty is reduced due to the improved state of knowledge. And those will be conditions in which it's going to be administratively and even politically difficult to say well, your friend who we had time to get to last year, under the old version of IREP, he's compensated. But unfortunately we have new information now and because we didn't get to your claim until this year, we've updated IREP and you're not eligible. But I'm sure there -- I would imagine in those situations there would be administrative decisions made so that we would try to preserve the maximum amount of fairness in the system.

I'm open to any questions.

DR. ZIEMER: Dr. Roessler wants to start the questions here.

DR. ROESSLER: Your last statement was so dramatic that I pretty near forgot my question. But you talked about the Pierce data and the changes that could occur. My concern when you were talking about it and looking at how the changes might affect the probability of causation were that you'd have to have -- feel that it's a really strong study before those changes could be implemented. But then you said that Dr. Land, in making his recommendations to NIH, was taking some other factors into consideration. And what are those other factors?

DR. HOFFMAN: Well, primarily what's been found in statistically analyzing the relationship of lung cancer, radiation and smoking is now the relationship is not dramatically dissimilar from what is seen for other solid tumors. And so it is the information for other solid tumors now that adds extra weight to the justification for the update.

What has happened is that the original Japanese cohort -- actually the incidence of smoking wasn't that high,

because during and right after World War II, cigarettes weren't that prevalent to the Japanese. It's the younger members of the cohort that began smoking excessively. And it's that signal that has now manifested itself into the more recent studies. Turns out now that the frequency of lung cancer in the Japanese cohort and that of the U.S. population is not as different as it once was. And accounting for these age differences in smoking, as well as the strong difference between males and females -- females don't smoke that much in the Japanese population, but most of the compromises to a healthy lifestyle occur in the male population. And so taking this evidence into account, the Pierce study has justified its updates and in my discussion with Charles Land, he considers this to be serious enough to consider the updates, primarily because there are groups, if we were not to update IREP, who would not be compensated.

But the prime evidence he's taking into account is the -- the additional evidence is the similarities seen for other solid tumors.

DR. ZIEMER: Jim?

DR. MELIUS: Yeah, thank you for a very good presentation. I want to go back to another issue. That's the issue of the worker populations and how we -- what we do about -- about them 'cause it seems to me that has a -- a lot of concern on the part of claimants and so forth, and there's always going to be sort of a -- a major criticism or concern about this -- this whole -- whole process. And now this question's for you, but it's also for the Committee and -- and Larry as to sort of how do we get engaged in a process that can start to address that concern. I think when we talked about this last time, part of -- one of our ideas was well, we need to -- NIOSH was going to update us, which I believe they'll do tomorrow about the worker studies underway, but I thought -- your presentation sort of triggered me to -- sort of some thoughts. How do we get this process go-- seems to me we need to have some ongoing effort to start to address the -- start to make some comparisons and to look at some ways that those studies could be utilized in IREP and utilized in -- if only to say that they -- you know, it's not ready yet, it's not time yet or

whatever, but it may be there are different approaches to doing it. You mentioned some which I guess -- again, made me think about this -- was the idea of what does it do to uncertainty and so forth rather than, you know, is the -- cohort's large enough or whatever and do that. So I don't know if you have any thoughts, Owen, or anybody else does on sort of how we get a process going that would start to -- 'cause I think it's going to take us some time to do this. It's not something we can do in a meeting or two, but it's something if we got somebody working on it, you know, maybe a year from now or several months from now we could have, you know, a product that we could start to talk about and think what might -- might be done. So Owen first --

DR. HOFFMAN: Well, the reason I include this in my talk is I recognize that the uncertainties in IREP -- they're not statistical uncertainties. These are more degrees of belief, they're more of a Baysian quantification of state of knowledge. And when we get into quantification of state of knowledge, all the evidence -- all the evidence available should be taken

into account. Currently because the Japanese data is the gold standard and because we based it on the 1994 data on cancer incidence -- I mean that's what we've benchmarked the risk assessments within IREP upon, but it doesn't mean that at some future date other datasets couldn't be brought to bear so that we have a more complete expression of the state of knowledge within the uncertainty estimates.

Now how to do this, whether one takes my approach and gives subjective weights to each of the independent studies, or whether one does a med analysis or whether other -- other types of approaches are used, I mean that's basically up to NIOSH, this Committee and the epidemiological branch of NIOSH in concert with Fadesh Amensei* I think to -- to undertake. And maybe some of this will be forthcoming within the update of BEIR VII.

DR. MELIUS: Yeah, just to follow up on that, is there some way that you've thought about this, Larry, of, you know, commissioning some group to do an evaluation or at least to start to pull some of this information together in a way that might -- and bring it to bear on this 'cause I've not seen that done in any sort of

systematic way.

MR. ELLIOTT: Right, we haven't done that, but we're -- the only reason why is we're anxiously waiting to see what the BEIR VII committee does. You know, once they come out with their final report, it's not only going to talk about where the States -- United States' Energy employees occupational health studies are at, it's also going to talk about the new -- the dose reconstruction for the LSS. That's going to be very interesting to see.

There's also radiobiology coming out of that review, so we're anxiously awaiting that. And dependent upon what that report says, yes, then we'll have to make a decision. Did they take it far enough, in our opinion? If not, then we need to commission, or perhaps under contract support, get somebody working on these things to pull this information together for use.

DR. MELIUS: Remind me that the -- our estimated completion for BEIR VII.

MR. ELLIOTT: Well, I talked just this past week with people on that committee, and it's likely to show up sometime next year -- and not early next year, probably

mid-year, if not later.

DR. MELIUS: No reflection on Dr. Land, but I just keep -- finalization of his work -- IREP keeps getting extended out also, so -- in true epidemiological report fashion, another...

DR. HOFFMAN: As you know, we're working closely with Dr. Land, and I think -- to be very honest with you, I would say it's out within six weeks.

DR. ZIEMER: Tony has a question.

DR. ANDRADE: Following up on the whole idea of just when something like this might be ready to come out, if you will, and to be evaluated for inclusion or consideration -- for inclusion in IREP, you know, Baysian statistics relies very heavily on having a good prior. But studies have shown, even Monte Carlo studies, on prior distributions that if you vary them somewhat, they're pretty robust so long as you have good basic data. So it may not require cohorts of tens of thousands or 10,000 to make an assertion about whether or not you've reached some sort of interval of confidence.

In the data you showed with respect to smoking --

light, moderate and heavy for males or females -- do you have any idea what sort of populations they were looking at, the number or --

DR. HOFFMAN: It was a subset of the full cohort. What -- I'd have to revisit the whole paper to say what fraction that -- it wasn't the full cohort. It was a fraction of the cohort, but I think that fraction was on the order of 30 percent.

DR. ZIEMER: Jim, you have another --

DR. MELIUS: Yeah, just back to the worker population issue again, I still think even given that time frame on BEIR VII that if NIOSH could think about some ways to get that process going beforehand that would not, you know, sort of undercut or be undercut by BEIR VII but be a way of starting to work -- make some progress on that 'cause I hate to put this off another three or four years before the -- the issue gets evaluated in some way. Now maybe it's not possible to do 'cause BEIR VII is so -- such a comprehensive relook at things, but I think it might be helpful.

Back on the smoking issue, I guess my question is -- for Larry and NIOSH is what are your thoughts on

addressing this? I didn't realize that Charles Land's completion was in six weeks.

DR. HOFFMAN: If it weren't for this, it'd be out now.

DR. MELIUS: Yeah, I know, I know. That's what I'm saying.

MR. ELLIOTT: Yeah, we were hoping it'd be out by now and we, too, have been in communication with Charles. And you know, it's been a three-way communication -- us to SENES and SENES to NCI and us to NCI. Let me assure the Board that we've not finalized any cases -- lung cancer cases yet where a smoker was found to be a non-compensable case. All our lung cancer cases that have gone forward have been compensable. We wanted to bring this before the Board because we knew the Pierce article was out. We appreciate Owen's working up some examples. It kind of starts us thinking about these kind of situations. We're very much interested in the Pierce paper. It's one paper, though. It's just one set of findings. And I think there's only 620-some lung cancer cases that were evaluated and only 300 of those had smoking. Is that right? Something like that? So -- to get back to your question earlier, so

yeah, we're looking at it. We're considering it and we're thinking through what we see there. That's about all we can say at this point in time.

DR. MELIUS: Press you on this a little bit, can -- can we say that it's something that we can -- should be ready to deal with at the next meeting or --

MR. ELLIOTT: I don't think we're going to be ready to deal with this at the next meeting if you're going to meet within the next two months.

DR. MELIUS: So what, six months from now? I mean --

MR. ELLIOTT: Well, I'm not going to -- I'm not going to give you a commitment as to when you're going to be -- we're going to be ready to present something to you. We've got a lot of legwork here to do. We're going to do that with SENES. We're going to do that with NCI, and we're going to reach out to other experts and get what -- what their thoughts are on this before we bring it to the Board.

DR. ZIEMER: Henry?

DR. ANDERSON: Yeah, this is -- perhaps is more of a technical question. It seemed on all of your odd graphs, like on the smoking things, you -- all the age

groups had the same confidence interval size, and I would have thought that, given the small number of cases that -- I mean the number of lung cancer cases in those people under age 40, there are people who would argue that's a different cancer than in older group, but I would have thought confidence intervals as you age ought to get narrower because of the larger number. And the other, of course, excess relative risk, is often driven by the denominator or the base background level as the background rate goes up, getting really a -- large numbers of excess relative risk is difficult, just -- I mean physically there you've -- everybody would have to have the disease if the background's low, so it is somewhat size of the population driven, and that's -- I just ask what your thoughts or how you might go about --

DR. HOFFMAN: Well, yes, and you remember initially I said I was going to give you some initial implications. Well, buried within that comment was the fact that the initial data that we had to start with in the Pierce paper doesn't explicitly give us the confidence intervals for all these categories. What they give us

are the confidence intervals for a different smoking category at age 60 to 70 at time of diagnosis of disease. Then they give us a table where there are just multipliers for the other categories, without confidence intervals. So to give you initial implications, it was just the simple arithmetic -- the multiplication that was done, so don't over-interpret the confidence intervals that are in the slides. Everything you say is true, and those are some of the things that Charles Land is dealing with is the age-specific confidence intervals that would be appropriate.

DR. ZIEMER: Okay. Tony?

DR. ANDRADE: Just to respond to Jim, my question earlier was meant to put this in context, especially when you're dealing with analysis -- the Baysian probablistic analysis. In other words, you do away with (inaudible) stuff. Only until -- and you don't know when this really is. Only until you have a sufficient prior distribution, one that's really populated with a lot of good data, and that can be jostled around via Monte Carlo techniques or whatever

so you change it around just a little bit, but the outcome of probablistic calculations give you the same relative confidence levels do you feel comfortable about the results of your analysis. And typically, you know, even after you've put together a prior, that sort of research and analysis takes somebody one or two years. So it's a tough science, but it gives ultimately better answers.

DR. HOFFMAN: And for those who have some knowledge in Baysian approaches, I just want to say that the uncertainties that we produced through IREP, these are -- and they're not statistical uncertainties. They are like Baysian uncertainties. More technically, they're informative priors waiting for the next dataset to come in to allow us to update. But the systematic process of prior update -- new prior update has yet to occur.

A REFRESHER AND UPDATE

ON REF'S ASSUMED IN IREP

DR. ZIEMER: Okay. Then I think we're ready to continue with the next part of this section, and Dr. Kocher is going to come to the podium now. His background is in experimental nuclear physics, now

senior scientist at SENES and has had over 28 years of experience in environmental health physics, including development and application of models and databases for assessing doses to the public due to radionuclides in the environment. He's developed the probability distributions of radiation effectiveness factors for different types of radiation to represent biological effectiveness in causing cancers in humans.

Dr. Kocher, glad to have you here to speak on this next topic, give us an update on REF's.

DR. KOCHER: Yes, thank you very much. I gave a fairly detailed technical presentation on this subject because it was completely new at one of your meetings in Denver early last July, and I can really summarize part of my remarks in about 15 seconds by saying that there have been no changes made in the information that was presented last July, nor have we received any information which clearly indicates that we made a gross error somewhere. So basically what I want to do today, because it is a difficult subject, is to give you more of a broad qualitative overview of what we did compared with the more detailed technical presentation

last time, and to particularly highlight what I called issues. And by that I mean areas where judgment in the face of poor data really came to the fore, and these indicate areas where possible future work might be helpful in improving our state of knowledge about this. Next, please. Let me just remind you what these REFs are. They are factors in the risk equations which represent the biological effectiveness of different types of radiation for the specific purpose of estimating cancer risks and probability of causation. These quantities are different from, but analogous to -- if you want to have a frame of reference for what these things are, they are analogous to quality factors and radiation weighting factors that are used in radiation protection.

But there's a fundamental difference between REFs and the radiation protection quantities. And that is that they take into account uncertainty in our state of knowledge. All of these REFs are expressed as probability distributions that are intended to represent uncertainty, state of knowledge, whatever term you like. And I would emphasize also that they're

subjective representations of uncertainty. The probability distributions that we've developed in many cases certainly are not the kind of frequency distribution you would get if you could actually do experiments to measure these things in humans. They're just our best representation of what we think we know. The radiation types for which we've developed REFs are listed in the next to the bottom line there -- neutrons, alpha particles, photons and electrons. Whenever you talk about biological effectiveness, you have to have a so-called reference radiation, which is the -- the baseline radiation for which you assume that the effectiveness is unity and everything else is relative to that. And we chose -- our reference radiation is high energy photons delivered acutely, because that's the radiations to which the A-bomb survivors were exposed. And as you've heard many times, the A-bomb survivors is the source of almost all of our data on radiation risks that are used in IREP to calculate PC.

Now I'm going to skip this slide and the next one, for those of you in the handout. These just go over the

risk equations that show how an REF is used to calculate risk. And I skip it because it's not really germane to my overview here about what we did and what the problems are. Just remember that REFs are things that are used to put biological effectiveness on a common scale for all radiation. So the main reason I don't go over it is because it's right after lunch and glazing eyeballs would result, and we can't have that. Okay. So I'm going to spend a few minutes just talking about how I went about this. As you may know, there's enough radiobiological literature in this area to fill this room, and we had no time or intention to go through all this literature. But fortunately, quite a few experts and expert groups have reviewed the radiological -- radiobiological data -- the quantity is RBE, stands for Relative Biological Effectiveness. This is what you get in basic radiobiological studies. There've been thousands of experiments to measure RBE for all kinds of endpoints, all kinds of organisms, all kinds of radiations. And fortunately this information has been extensively reviewed by groups like the NCRP, the National Radiological Protection Board in the UK,

experts like Tori Kromse* who did the careful evaluation of all the data for tritium, so we basically relied on the reviews by other groups.

Now they did not come up with probability distributions of the data. We looked at the summaries and evaluations of data to derive our own subjective probability distributions. This was not done for us. Most of the data that we reviewed came from studies in small mammals like the mouse and beagle dogs. Lots of data on mammalian systems, cells of mammals -- human lymphocytes, for example, was a -- is a common biological organism that's studied. Unfortunately, very limited on humans to address questions of biological effectiveness of different radiations. And really the key to all of this is that we have to use judgment in applying the available data on RBEs for a variety of systems and a variety of biological endpoints to say that represents the biological effectiveness with respect to cancer induction in humans. That may be a substantial leap of faith, but we cannot really do very much about it.

Next, please. Okay, I'm just going to go through the

different radiation types very quickly. I'm not even going to present any numbers, although if people are interested in knowing well, what did you assume for alpha particles in leukemia, I mean I have the numbers with me. We can discuss any of this in detail that you want.

Starting with neutrons, first of all there's clear evidence from a lot of studies in mice that there's a difference in biological effectiveness for neutrons if the endpoint is solid tumors versus leukemias, and so we developed separate probability distributions for those two types of cancers. The REF is generally less for leukemias than for solid tumors.

We know -- we have some indication from studies, and calculations certainly indicate, that the REF for neutrons depends on the energy. I mean there's a wide range of neutron energies that are potentially relevant to exposures to any group that you're interested in, ranging all the way from thermal neutrons to really high energy neutrons if you're concerned about astronauts and people like that. So we developed REFs for three different -- actually five bins of energy,

but only three different distributions of REF, because two of the pairs were the same. The highest REF is the first on there, the fission neutrons, the category from 0.1 to 2 MeV. Somewhat lower REFs for the second line that you indicate there, 10 to 100 keV to 2 to 20 MeV; and the lowest REF for less than 10 keV and greater than 20 MeV. And the reduction on average was about a factor of two in going down each of those steps, so the bottom line is about a factor of four or less, on average, than for fission neutrons. But of course we have uncertainty in all of this.

In addition in the calculation we include -- we have a small increase in the REF for either solid tumors or leukemias and at any energy under cases of chronic exposure. And this accounts for what's called the inverse dose rate effect. There's some evidence from studies in animals that if you take two experiments where you deliver the same dose, if in experiment one the dose is delivered acutely and experiment two the same dose is delivered chronically, there is some evidence that the response is higher in the group that gets the chronic dose, so it's an inverse dose rate

effect. The biological effectiveness goes up as the dose rate goes down. And there's a small correction amounting to about 40 percent on average for chronic exposures.

Next, please. Next is alpha particles. Here again we have separate distributions for solid tumors and leukemias, based on some evidence, again, that the REF is substantially higher for solid tumors than it is for leukemias. The difference between alpha particles and neutrons is that we do not have an energy-dependent REF. It's the same for all energies. Basically we're concerned only about -- so far we're concerned only about alpha particles from radioactive decay. And Mother Nature was kind to us, the energy range over which these vary is quite narrow. It's like 4 to 8 MeV, roughly.

We also included a very small factor to account for possible inverse dose rate effect. Here again the data are not conclusive as to whether it's real or not, especially at the doses and dose rates we're interested in, but there's a small effect that averages, I don't know, 20 to 30 percent on average. And this is applied

in all cases, because all exposures to alpha particles from internal emitters are chronic.

Next, please. Well, this highlights what was one of our real areas of challenge. It turns out that alpha particles in leukemias is one of the areas on which we do have potentially relevant information from studies in humans. The unfortunate aspect of this information is that it's totally contradictory, and so it leads to, you know, a need to really provide judgment to what you're doing, and I just want to take a second to discuss the problem here.

There are basically three datasets that we looked at, and the first two on there are datasets involving humans. Number one there is this group called the Thoratrast patients. These were some patients in medical studies that were administered a special kind of thorium called thoratrast, and there have been health studies, follow-ups on these patients over the years, and this group of individuals, taken as a whole, shows a clear excess of leukemias compared with an expected rate in an unexposed population. There's clear evidence that this Thoratrast administered to

these people has led to increased incidence of leukemia. You get this by comparing the leukemia risks in this group with the leukemia risks in the A-bomb survivors that were exposed to high energy gamma rays, and from that you can kind of infer an REF. And we developed a -- as you see there, a 95 percent confidence interval of the REF between 1.0 and 15 based on these data. You know, shows a -- shows a clear effect.

But there are other groups of human populations. One is the famous radium dial painters. Second is a group of medical patients that were administered radium-224, and in this group of patients there's no excess leukemia of any kind been seen. In fact, if you assume that the standard ICRP models for calculating dose to bone marrow from radium in bone, and if you assume that those standard ICRP models calculate dose to bone marrow correctly, you would infer an RBE for alpha particles and leukemias that's certainly less than one. If you ignore uncertainty, you would infer an RBE of zero.

So in the case of the Thoratrast patients we see a

clear effect. In the case of the patients and other people administered radium, we see no effect.

Well, what I personally think the important issue here is that in those two cases the dose is administered in quite different ways. Thoratrast is a colloidal suspension of a thorium compound, and that suspension -- that compound tends to remain suspended in bone marrow for a substantial period of time, so there's a pretty good chance that the radiosensitive tissues in red marrow are being irradiated in the Thoratrast patients.

Now of course radium -- its deposit immediately on bone surface and then over time is incorporated into mineral bone, and so you're basically irradiating bone marrow from the skeleton and not from the marrow itself, and it's entirely possible that the reason that you don't see any leukemias in this population is because the alpha particles which have very short range are not irradiating the tissues that you're interested in. But I don't know. You know, my -- basically what I'm saying here is that the dosimetry in those two cases is quite different, and that could be the explanation for

this.
A third piece of information has to do with the data for fission neutrons. I mean it's been widely held that fission neutrons and alpha particles -- and there's a lot of evidence for this -- are roughly the same in terms of biological effectiveness. So you could infer that the REF for fission neutrons in leukemias ought to apply to alpha particles, as well. And for neutrons you'd be fairly certain that you were irradiating the radiosensitive tissues because they -- you know, they penetrate the body easily.
So what we were faced with here is three different sets of information, two of which are on humans and they're directly contradictory. And the way you handle this, in our view, is not to say well, I'm going to pick the one that I think is best and go with it. What we do is give a subjective weight to each one of these as being plausible.
Now those numbers -- 50 percent for the Thoratrast patients, 25 percent for the other human populations and 25 percent for fission neutrons -- that's, you know, to be clear about it, fairly arbitrary. It's

what gives you a warm fuzzy feeling, and it's certainly arguable about that. And I'm going to return to the issue of this in my later remarks, but this is an example of an area where judgment is absolutely essential. You have to take data and try to resolve and figure out what you think it means.

Next, please. This is an important curve. We're moving now to the case of photons. This is a calculation of the quality factor that was done by the ICRU about 15 years ago. Our reference radiation, which is high energy gamma rays, sits right here on this curve. The calculation shows as you go down in energy at about 200 to 250 keV, it's about -- you reach a plateau where the quality factor is about twice that what it is down here, and below about 30 keV it continues to increase (indicating). Now we did not use this curve to infer what the REF for low energy photons would be. We used this curve to infer over what energy ranges would our assumed REFs apply.

There are lots and lots of data for what's called orthovoltage* X-rays, and that means X-rays where the tube potential is about 180 to 250 keV, something --

kilovolts, somewhere in there. But it turns out that that's not the energies of the X-rays, of course. The X-rays on average have substantially lower energies. And typically the average energies from these high energy X-ray machines are about 60 to 70 keV, so they fall in here. So there's a lot of data in this energy range, and we use this curve to assume that whatever REF we inferred for photon energies down here would apply up some plateau here. And similarly, there's no data down here below 30 keV, and we used this curve to imply an increase.

Next. Now for these -- these intermediate energy photons, the data -- the energy range for which there's a lot of data for higher energy X-rays. This was another case where we had to make some inferences based on information which could lead to different conclusions if you just took one dataset by itself. There's a lot -- the only studies of X-rays relative to gamma rays per se that we found have to do with induction of dicentric* chromosomes in human lymphocytes, and I'll discuss later possible weaknesses with this dataset. But these data clearly show that

for this endpoint that the orthovoltage X-rays are clearly biologically more effective than high energy gamma rays, without exception -- average value around two and a half, something like that. The confidence interval -- well, this is not the confidence interval for that dataset alone, but between one and about six was the confidence interval for that dataset alone. We modified that using what I called indirect inferences. And these -- let me give you an example of an indirect inference. Somebody is doing a study of the biological effectiveness of high energy protons, say. And that investigator does two studies, one in which the reference radiation is high energy gamma rays, and he does another study of protons in which the reference radiation is X-rays. Well, you can compare the RBE that he gets from those two studies and infer an RBE for the X-rays, 'cause he gets a different answer for his protons depending on what the reference radiation is. And by making a comparison, you can -- between the two reference radiations, you can infer what the RBE for X-rays was. And it turns out that there's about -- I don't know, ten or so studies out

there that we found reviewed in the literature where you could make an inference. And these studies all showed a clear indication that X-rays were biologically more effective than high energy gamma rays, without fail.

So we combined those two sets of information together to come up with a 90 percent -- 95 percent confidence interval between one and five, based on shall we say non-human data.

But there's another set of information out there, and this is what Iulian Apostoaei talked about this morning, information on induction of thyroid cancers in children especially, because there are data for the Japanese A-bomb survivors that were exposed to high energy gamma rays, and there are lots of childhood studies where children of various ages were exposed to X-rays, and you can compare the risk per unit dose, the ERR per sievert, basically, for those two studies. And what Iulian showed is when you look at the dataset, you really don't see a statistically significant difference between the risk of thyroid cancer in the A-bomb survivor children and the risk of thyroid cancer in

children exposed to X-rays. You don't see a statistically significant difference. And from that we inferred that an equal biological effectiveness between these two radiations could not be ruled out.

Now the truth of the matter is, if you look at these data and you take the statistical uncertainties without bias, without subjective judgment, it neither refutes nor supports an assumption that the biological effectiveness is the same, it neither refutes nor supports an assumption that they're different. But we used that information to assign a relatively small weight to the possibility that the biological effectiveness is the same.

And there's similar information, although weaker, for other cancers. If you look in the latest UNSCEAR compilations, for example, they don't show any difference in the ERR per sievert between childhood exposures to X-rays and -- or adult exposures to X-rays and exposure to gamma rays in the A-bomb survivors. So here's another case where we apply judgment to say we're going to give 75 percent weight to this dataset which clearly show an effect, and we give 25 percent

weight to this other dataset that is inconclusive. Next, please. For photons less than 30 keV, remember the curve from the ICRU that -- the quality factor increased below 30 keV? We found no data in that energy range, but we assumed that that curve described an increase relative to the intermediate energy photons from that calculation, but we assumed that the correction was energy independent. We did not put an energy-dependent correction in there. It was described by a triangular probability distribution.

Next, please. Electrons. There is a wealth of data on the biological effectiveness of beta particles from tritium decay. There's virtually nothing that we've found on any other kinds of electrons. The problem here is that the energies of electrons from tritium decay are very low. The average energy is only about 6 keV, and we'd be curious of course about the biological effectiveness higher than that. And we had to have some way to say over what energy range can we apply the information on tritium beta particles, 'cause it surely doesn't apply just there. It may apply at somewhat higher energies.

And so we used the following line of reasoning. When you do a study to measure the RBE of photons, what you are actually measuring is the RBE for the secondary electrons that are produced in first collisions of photons with atoms. That is what you are really measuring. So if you know, for example, that photons of a certain energy have an increased biological effectiveness, you can derive what the energy range of those electrons is that should have the same biological effectiveness, and that's basically what we did. All you have to know is what's the energy distribution of Compton electrons as a function of photon energy, what's the energy distribution of photoelectrons as a function of photon energy, and what's the relative importance of those two processes.

There again, nature was kind. Either the Compton effect is almost everything or the photoelectric effect is almost everything, and there's a small energy region of up around 15 keV actually where they're more or less the same. So you basically use what you know about how photons interact to infer something about electrons. And from this, to make a long story short, you assume

that the tritium data would apply at energy -- any energy less than 15 keV, based on how the photon quality factor works, and we apply this to average beta energies less than this, or energies of discrete electrons less than that.

These problems of Auger-emitting radionuclides in DNA, this is a tough problem. Let's just hope that the DOE program doesn't encounter this very often. You basically are going to have to get help from experts in microdosimetry I think to work this out.

Next. Well, I talked about how you can, you know, use your knowledge of Compton scattering in the photoelectric effect to infer REFs for electrons where you don't have any data, and what is easy to show is that this 30 to 250 keV range where we have an elevated REF for photons, that corresponds to average electron energies between about 15 and 60 keV.

However, and I think this was a reasonable decision, even though you can do this calculation and you have a lot of confidence in it, we have not yet adopted an REF for this intermediate electron -- energy electron range. We still assume that it's one. And there were

two reasons for this, 'cause we lacked data in two areas.

First, we don't really have any biological data on photon energies greater than about 70 up to about 250. Remember, I emphasized the point that these orthovoltage X-rays, the average energies are mostly around 70 keV or below, so we don't have any firm evidence at the higher energy photons that we're interested in. And secondly, we don't have any data on electrons other than tritium beta particles. Where this energy range might possibly come into play is if you had anyone exposed to carbon 14. I think nickel 63 is another one where the betas fall in this energy range.

Next, please. Okay, now I'm going to go back through each of the four radiation types and revisit what some of the issues are that future activity might be beneficial. Starting first with neutrons, we found no data on RBE at the lowest energies at the highest energies, so we basically had to assume that the assumption by ICRP that the RBE was about four times less than it was for fission neutrons, we had to assume

that that provided a reasonable central estimate. Of course we included some uncertainty in this extrapolation, but it is an assumption on -- for which there's basically no data that we found. In my checkered career I actually got a few of these. I used to work in an accelerator lab that handled tritium and we had deuterium beams and they give high energy neutrons.

There are a few data on these intermediate energies and the somewhat higher energies compared with fission neutrons, and it turns out that some of the data show a decrease, as expected by the calculation. But there's some data that show no effect. So the database here I would characterize as weak. There's no direct evidence that the correction for an inverse dose rate effect should be applied under conditions of chronic exposure. This is not a big ticket item. It's only, you know, 30 to 40 percent on average.

Our REF for the lowest energy neutrons ignores the possibility that the REF could in fact be less than one, could be substantially less than one, like maybe .5. And the reason is, the lower bound of our

distribution is at one, but the reason that it could be less than one at these energies, when a neutron of this very low energy impinges on tissue, the radiation that causes most of the dose eventually is high energy photons from capture by hydrogen nuclei of the neutrons, and those photon -- that photon energy is 2.2 MeV, and that's quite a bit higher than the cobalt 60 gamma ray energy of about 1.3 MeV. And calculations have suggested that the effectiveness of the 2.2 -- that the effectiveness continues to drop as the photon energy increases. But it at most would be a factor of two, but probably not that much, but we have no accounting of that in the present situation. Conversely, the REFs in humans may be overestimated when the neutron energy is -- no, the REFs may be underestimated when it's greater than .1 MeV. What's going on here, in the mammal studies most of the dose is delivered by the higher LET radiations because the distance through tissue that you have to traverse is relatively small. In humans you have to go through more tissue, you get more high energy photons that are delivering the dose to deep-lying organs and tissues,

so that the animal data may in fact overestimate the REF in humans at these energies, and we've made no accounting for this.

Now the ICRP has done a lot of calculations of this and what they show is that this effect is a very complicated function of the neutron energy, the particular organ being irradiated and the irradiation geometry.

Next, please. Alpha particles. I talked at great length about the problem of what's the REF for alpha particles and leukemias. It would be interesting to resolve the discrepancies in human data. My basic approach to coming up with our hybrid distribution was to say look, you probably have trouble with your dosimetry models for alpha emitters in skeleton, but I don't think you should bury considerations of biological effectiveness in your problems in dosimetry. If you've got a problem in dosimetry, go fix it. What we want to know is, if the dosimetry is done correctly, what's the biological effectiveness of alpha particles. And so that's the approach we took. But there's a lot of work that could be done here, for sure.

Again, is the inverse dose rate effect real or not; this is a very small deal. Another deal that I don't think is very important is that almost all the data on RBE for alpha particles, the reference radiation was high energy beta particles delivered chronically because that's the way alpha particles deliver dose, so there's no data relative to what we have assumed as the reference radiation. I don't think this is a big problem because there is some evidence that these high energy electrons and high energy photons have the same biological effectiveness as we have assumed.

Next, please. What about photons? There basically is no animal data on X-rays and cancer endpoints. There are these studies of cellular effects, effects on chromosomes, things like that, but no data on cancer endpoints. And one of the criticisms that we got when we used the human lymphocyte data to infer this is, you know, that okay, induction of these chromosome aberrations, that's not cancer yet. And you've all heard the stories of you can see chromosome effects in all these populations that live in very high background areas, but you can't see excess cancers. So it would

really be nice if there were animal data on the difference between X-rays and gamma rays for cancer endpoints. We're assuming that the cell data applied. I mentioned before, no data at the lowest energies, and these energies between 70 and 250.

Iulian again this morning talked about the importance of fractionation of X-rays and childhood exposures. Remember we gave 25 percent weight to an assumption that there's no difference between X-rays and gamma rays based on the human data, the human childhood data. Now what Charles Land has done and what Iulian recommended be incorporated is basically say look, what you see in those data is the law of compensating factors. There is an increase -- there should be an increase in effectiveness of X-rays in the childhood thyroid cancers, but it's masked by the DDREF because those exposures were given in a protracted fashion rather than acute. You know, if the RBE is two and the DDREF is two, they cancel and you see no effect, which is what the data show. So if we really decided that the childhood thyroid data really represent high energy photons delivered acutely, that could call for a re-

investigation of the assumption that 25 percent rate should be given to an assumption that there's no difference. It would tend to reduce the weight that's given to this assumption because you're now assuming that the childhood data really do show an effect when you consider the fractionation problem.

Next. The electrons -- there's a lot of data on various -- on a large number of different stochastic endpoints. There's relatively few data on carcinogenesis endpoints, and on average, the RBEs tend to be a little bit lower than for other endpoints. Of course, given the preponderance of data, we gave the greatest weight to the non-cancer endpoints, so this could be the same problem that we found for photons. But still, these data in general show some increase, just less on average than for other endpoints.

No data on RBE at energies higher than tritium beta particles, and the REFs for these very low energy Auger electrons -- these typically are less than one keV, and they are copious in decays of some radionuclides, these ones that decay by so-called electron capture decay. And when they are incorporated into DNA, the RBE could

be 40, 50, 60, 100 -- I mean it's huge, and so if we encounter any situations like this, care is really called for.

Next, please. I was asked to speculate on what we might develop that we don't have. It's conceivable that in some programs, perhaps not this one, that you would need REFs for protons and heavy ions including recoil nuclei and fission fragments.

Do we have any cases of internal exposure to Californium 252 in this program?

DR. NETON: Not yet, no.

DR. KOCHER: That'll be a hoot if one of those comes in, because I -- I swore I was going to look up the number and I failed to do it. I think the spontaneous fission branch for Californium is like nine percent, so you know, good luck.

Next. And those fission fragments deposit a lot of energy over a short distance.

The last point I want to mention is something that Brian Thomas mentioned this morning, is that I developed this new help file to guide users in selecting radiation types. The menu has 11 different

types of radiation, but you're not necessarily going to have the data in exactly the form that IREP wants, so this request came from NCI, not from NIOSH, because NIOSH and its contractors knows -- they know what IREP wants and they presumably know how to do it, but you know, NCI is passing essentially the same version of this code over to the Department of Veterans Affairs to handle claims by the atomic veterans. And since I served on this committee you're going to hear about in the next presentation, I knew that the medical guy at the VA is not getting the information that IREP wants. I mean I know this. And so I worked up a fairly detailed help file, basically to help the medical officer at the VA do this correctly. But it also should be of general use for anybody who wants to get into IREP and play around with it, but the dosimetry information they don't quite know what to do with it. And I knew this going in when I worked on these REFs, but especially was impressed upon me when I tried to develop a help file for internal exposure.

It is clear that if you're not given the information that you want, if you're going to make some assumptions

about what radiation type to enter, sometimes it's straightforward, but it's easy to encounter cases where you absolutely have to have your fanny screwed on straight. You've got to know about radioactive decay, you've got to know about biokinetics, you've got to know about sites of deposition and what organs are being irradiated. You've got to know a lot. There are radiations which could be encountered where four different radiation types are emitted in the decay of that radionuclide and they all contribute somewhat significantly to the dose. You know, these are -- external exposure I think, relatively speaking, is a piece of cake. But internal exposure -- I won't say problems could arise. You have to know what you're doing. You can't fly by the seat of your pants. But again, this should not be an issue for NIOSH and the contractors because they presumably know all this. But I'd be interested in hearing a presentation sometime about how they do all this, just to make sure. Thank you.

MR. ELLIOTT: Thank you. Thank you, Dr. Kocher. It was a very illustrious, informative presentation. I

think it's always good to take us all back -- the Board as well as NIOSH staff -- in understanding and realizing what the scientific basis and underlying assumptions are on -- that we come to grips with on radiation effectiveness factors.

Are there any questions for Dr. Kocher? It was all that clear.

DR. KOCHER: Stunned them again.

MR. ELLIOTT: We're stunned. Well, I'm sure that you'll be able to get him in a moment, if you wish, on a one-on-one basis.

DR. KOCHER: I'll be here till 8:40 tomorrow if anyone wants to talk to me.

MR. ELLIOTT: All right. In the absence of the Chair, who had to excuse himself, you're at a break. Be back in 15 minutes.

(Whereupon, a recess was taken.)

DR. ZIEMER: Before we listen to our next presenter, I want to remind members of the public that if you do wish to make comments during the public comment period which will be at 4:15, please register at the table in the back with Cori. There's a sign-up sheet back

there. We need to have some idea of how many wish to speak so that we can allot the time accordingly, so please do that if you haven't already.

NAS REPORT ON REVIEW OF DTRA

DOSE RECONSTRUCTION PROGRAM

Now our next presenter will be Dennis M. Schaeffer, better known as Mike Schaeffer. Mike Schaeffer is here representing the dose reconstruction program of the Defense Threat Reduction Agency, and more particularly he's going to take a few minutes and tell us a little bit about the newly-issued report of the National Academy of Sciences, and you have in your packet a pre-publication copy of the executive summary. The full report will be out soon, I guess -- maybe Mike will tell us that and there'll be an autograph party at Barnes & Noble's on that, Mark -- or Mike?

MR. SCHAEFFER: Probably around June.

DR. ZIEMER: Okay. Well, anyway, please welcome back -- Mike's been with us before, and please address the Board at this time.

MR. SCHAEFFER: Thank you, Dr. Ziemer, for the introduction, and I'd like to brief just at the very

top level the recent report that was released by the National Academy of Science on DTRA's dose reconstruction program.

I apologize for not having any slides today because this was given to me at short notice, and so I'll try to be brief and take you through the -- just the top level details.

This particular study was commissioned two and a half years ago as a result of a Congressional mandate following on the heels of a General Accounting Office audit of the dose reconstruction program. And one of the major recommendations of the General Accounting Office was should or should there not be continuous oversight that had been somewhat lacking over the years in our dose reconstruction program. Keep in mind that we have been constructing doses on the order of over 20 years during the course of our program that started in 1978. So this report represents an important milestone, not only where we are in the program, but encompasses the entire experiences that we've had in this program from day one. Until your program was created for the Energy workers, this was a one-of-a-

kind program. And I just wanted to remind you of all of the things that have happened over the years have been somewhat embryonic in the early days and developing over the later years, and I believe that was pretty well the point I made in the overview of the program I gave back in August of last year.

The dose reconstruction study encompassed taking a sample of 99 dose reconstructions performed by Defense Threat Reduction Agency and its predecessor agency, Defense Nuclear Agency, mainly by its one contractor, SAIC. Basically some of the issues the committee had to deal with were basically three issues, and these have been nagging issues over the life of the program: Does dose reconstruction represent a valid process. Second of all, how does that valid process help in working with a compensation program, in this case run by the Department of Veterans Affairs. And the third most important issue that ties both our program and the VA program together is is there sufficient benefit of the doubt being exercised through this program that gives the veteran the best chance for compensation. And of course this report represents a very, very

comprehensive study if you read between the executive summary and the beginning and the conclusions to the end, a very in-depth look at every detail that goes on during the course of our constructing doses.

The National Academy had four basic charges associated with dose reconstruction, and then one charge of course that applied to the entire program. I will summarize the four basic charges that they had before them.

The first charge was are the doses accurate. And the second charge is are the doses as they are reported to the veterans and the Department of Veterans Affairs, are they reported accurately. The third charge was are the assumptions reasonable and credible with respect to how we estimate the upper-bound doses. And the fourth charge was are the data -- and when I say the data, are the records and the historical reports robust enough in terms of allowing dose reconstruction to be conducted and to be conducted accurately.

So I'm going to hit each one of those very quickly as regards what the Academy found. The first, are the doses we reconstruct accurate. The basic finding was the average value that we construct for our external

doses, while indeed they may be accurate and valid, the upper-bound estimates that we provide for those doses likely are not true upper bounds at the 95th percentile. So it indicates that we have some room for improvement there.

As regards internal dose, it said that for the most part the doses that we estimate for inhalation to organs, in some cases and many cases are representative upper-bound estimates. However, it did mention a few scenarios where the upper-bound estimates that we provide for inhalation doses are perhaps severely underestimated. And they specified the particular instance of where we construct doses for areas where fallout that's already been deposited on the ground from a previous test is impacted by shock wave of a current test in that we don't fully account for all of the resuspension of the previously-deposited fallout in those instances. And of course they don't affect a large group of people, but nevertheless it's enough that we need to go back and relook at doses we constructed -- internal doses for those populations, or subpopulations.

It also said, internal doses, that we don't pay much attention to performing ingestion doses. But the perception there is that the ingestion doses do not form a large part of the entire internal dose, and the consequence of our not paying much attention is probably not very consequential to the entire dose to the veteran internally.

The next charge, are the doses reported accurately. The answer is the doses we report to veterans and to the Department of Veterans Affairs are indeed accurate. However, they feel that -- the Academy feels that we can do a better job in communicating the upper bound of uncertainties, what does this exactly mean, and also that the VA in turn can do a better job in communicating what the actual risk from that radiation really is in terms of inducing cancers and other diseases.

The third charge, are the assumptions credible and reasonable, and this is the area where we received probably the most criticism, that a lot of the assumptions we make for upper-bounding doses are not credible and reasonable, and that's from two

standpoints. Scientifically we've not taken into account a lot of the techniques that are available today to do uncertainty analysis on the 95th percentile value. We have focused over the years on providing a good reasonable estimate -- accurate estimate on the central tendency value, but we've not paid much attention to the fact that 95th percentile values also have distributions of uncertainty.

On the other hand, the non-scientific part of the program, have we incorporated in every case over the breadth of the program all that the veteran could give to us in the way of personal anecdotes and information, and we've not, to a great degree, done that consistently across the life of the program. We do it better today than we did back at the inception of the program. Do we do it the best way possible in terms of where we're going in the future? I think that's a scenario where we can do even better still in terms of making sure that we have consistent ways of communicating with the veterans and gaining all the information that they have as insights to the process. And also what they did.

The fourth charge, are the data accurate and robust enough to support dose reconstructions. The Academy found that the reference sources are sufficient and adequate to allow dose reconstructions to be derived from available historical data. In fact, they commented that data are rather -- rather extensive and available to perform dose reconstruction.

Of course where does this go? One of the items I believe I briefed to you in August of last year was should the DTRA dose reconstruction program have an oversight committee very much like the Energy workers program. And that's the subject of the last charge the committee had is did they find it appropriate that we should have an oversight over the dose reconstruction process, independent of the agency. And the answer came back yes, and this is sort of where we are today on the program, that makes it very much indicative that we need to be involved in the type of business you're doing because, rather than you having the lessons learned from us, I think this is the point at which the roles between the two programs are going to reverse and that we're going to look to be doing very much the same

thing that the Energy workers program is doing to actually improve our program.

Some of the comments we had is we have a plan of course to put the recommendations into effect. We believe of course that the Academy did a very, very thorough and scholarly piece of work in investigating our program, and some of the suggestions in there -- or all the suggestions are excellent suggestions that will help us make the program better. And of course the very most important thing with implementing this particular -- recommendations of this report is we need to be able to do the best job we can for our veterans who were exposed during the atomic test era and the post-war occupation of Hiroshima and Nagasaki. And we believe that this particular study will take a 20-year-old program and push us into the future, should there be means to allow us to continue this program.

I'll take any questions.

DR. ZIEMER: Thank you very much. Let me comment before we have questions, and that -- the comments are as follows: First of all, this item was added to the agenda very late, as many of you know, and the reason

was that the report just came out. And it's our hope that we can have a more in-depth time to focus on this report, perhaps even at our next meeting, and perhaps invite the Chairman of the Academy committee, who I believe was John Till -- or else one of his colleagues -- to address the group and go into the report in depth. Since it's a report of an Academy committee, that might be worthwhile.

It probably would be inappropriate for us to put Mike on the spot and ask him to go into any depth today in terms of our questioning. I think I would just like to limit the questions -- one or two brief questions if you have them, and then we're going to move on to our next topic. But we do appreciate at least giving us this initial glimpse of the nature of the report. It has I think the -- certainly the recommendations that the committee made are very pertinent I think to us as well to look at what they recommended for that program and see what kind of parallels we might have with our own program here in terms of the oversight, monitoring issue, quality control issues, that kind of thing -- and communication with the claimants and so forth.

But we have several questions again. Please keep them brief and let's not try to get into depth on this report today. Okay, Gen -- we'll just go down -- around the table here.

DR. ROESSLER: Mine is not a question but a comment, and I think it's lessons learned for us from this report and I think we really ought to study it in some detail because there are a lot of them. My impression when I read the comments, the deficiencies, is that this program already has taken -- you know, is doing these things, has -- has learned from it. But I think the thing that impressed me as the committee looked at the data and talked about quality control, illegible data, lack of standard operating procedures, and I think that this -- certainly in this program is in effect. But we as the Board should make sure that we continue to monitor, especially I think the standard operating procedures.

DR. ZIEMER: Thank you.

DR. MELIUS: Yeah. Yeah, I thank Larry for putting this on. I was the one that requested it -- short notice -- and others may have, also, but appreciate

that. And also, just to echo Gen's, I think it's -- there are things that are underway here that sort of obviate some of the potential problems in the program, but one thing I have trouble with the report was -- from the executive summary and what we've heard about it is sort of what were the more important findings? It's a typical Academy report in that we've found a problem here, then usually later in the paragraph it's buried in saying but it really wasn't that important, you know. And it's very hard to judge, of all the different sort of potential problems they found, what were the more -- you know, most significant, at least from your perspective in trying to address, and then I have a follow-up question.

MR. SCHAEFFER: I think the most significant, and Gen touched on it very briefly, that I think underlies the entire program in terms of moving it forward is you look at the life of the program over the last 25 years, there's been various forms of two-way procedures. Of course better now than they were back then. Likewise, SOP, now much better than of course back when we started the program, where admittedly some of these

procedures were lacking. And I think the way forward here is of course the science and the art of developing QC procedures and SOP of course have evolved over the years, and this is where we need to get back into the queue and actually start developing what are those more extensive procedures that you see at DOE establishments or that you see the U.S. Navy Nuclear Propulsion program use in conducting their work. So there's all sorts of paradigms that we can draw on today that I think would be most important for us to embrace in their entirety, but this is an area where, number one, I think we need to concentrate a lot of effort. It's also one where we can also institute actions right away, so that provides a good opportunity.

Let's see, what's the second issue you brought up?

DR. MELIUS: Yeah, just one -- I don't know if you have any preliminary thoughts. One of the recommendations and findings that struck me was this issue of how you take into account the veterans', you know, personal recollections and information they provide and how to you systematize that into the -- your follow-up and provide the documentation on that. Any thoughts on how

-- I know that's sort of a moving target, but any thoughts on sort of where you will go with that particular issue?

MR. SCHAEFFER: That of course represents the next equally important area. I think there's three issues that are important. The first we just talked -- first two we talked about. This is an area where we've not been consistent in our practices over the years. Again, the Academy report was written in the vein that they took the look back to 1983 on some of these doses, clear up to 2001. And given the fact that there's better degrees of performance here as time marches onward. But one of the areas I believe we can do even a better job is talking to the veterans, taking into consideration what they say. And this is a very, very big gray area in terms of our having to work probably in a closer partnership with the Department of Veterans Affairs. It's very, very important -- very, very important that we get the veteran's statement up front in this process. And not only is it important that we just get a written statement, that we also have the opportunity to be able to go back and talk to the

veteran about that statement, get into a dialogue up front in our process before we even pick up and do a dose reconstruction. Although we're doing many of these things today, we need to probably do them even greater emphasis. And I would say part and parcel with the QA procedures and SOP, we need to develop exactly what are those processes we -- that we're going to do to extract every last bit of information we possibly can from the veteran.

The second area that goes along with that, again, are assumptions always valid. I think we need to do something very similar that is done in the NIOSH program in that we need to sit down and spell out the basic assumptions prior to our doing any mathematics to assign a dose to the person, either from available dosimetry or other radiological data, which the Academy of course found -- finds is very robust in terms of being able to allow us to do the process. So we need to knit those two parts together very, very intimately much better, and I think even in terms of eliciting a response from the veteran is -- this is what we've got, will you shake hands with this so we can move forward

with the dose -- realizing again that's going to be a very, very precarious process in that some people, no matter what we do, no matter how well we make assumptions in their favor, may not agree with them.

DR. ZIEMER: A comment here and then we'll go on --

MR. ELLIOTT: Can I go first? Just for the benefit of the public that's here today, this is a pre-publication copy. We've provided the Board with the executive summary and the title page. The public can go to the web site, www.map.edu, and they'll find this report as a pre-publication copy. Once the hard copies are available, we'll solicit interest from the Board members and purchase you a copy for reference, for your benefit.

DR. ZIEMER: All right. Thank you for that comment. This is not a NIOSH document that we can make available to the public. It's not a government document, so -- but it is available on the web site if people want to read it.

Okay, Mark and then Tony.

MR. GRIFFON: Yeah, I think a couple of my questions were actually captured, and I had several, but I will,

as Paul suggested, save some of the more detailed ones. One thing I wanted to ask about, there's a reference further in the report -- page 127 they talk about the exposure profiles and they -- there's a conclusion that 20 of 99 of these exposure profiles were found to be -- have inadequacies, I think is the phrase -- I'm paraphrasing. And yet the overall conclusion, as you stated, in the executive summary is that the data was overall adequate. Is that consistent or am I -- am I misreading that? The exposure profiles I believe were used for the individual dose reconstructions.

MR. SCHAEFFER: I think the basic conclusion the Academy made is sound, based on the examination they made. We'll admit to you that if you don't read it from cover to cover and digest every scientific detail, you'll probably lose the flavor with actually how it relates to the overall recommendation or conclusion. So I would not say based on the 20 that you looked at that necessarily they were full-blown inadequacies. There were probably lots of gray areas.

MR. GRIFFON: I gue-- the reason I'm reflecting on the exposure profiles is because of the working group's

efforts here, too. I just want to find out, from our perspective, what we need to build into our system. But do you recall why -- and maybe this is putting you on the spot too much for the detail, but why there were so many inadequacies in those exposure profiles and are -- is anything -- have you reflected on ways to change that or has that been maybe modified already, how you do yours --

MR. SCHAEFFER: I believe that that's going to be taken up into the holistic approach we take to correct QC, QA, SOP, talking to the veterans. I think that that's very, very important that when we do upper-bound uncertainties, for instance, it's not just a scientific value, it's a part of -- considering all the data from the veteran, if the veteran says he's within 100 yards of ground zero but there are no available historical reports that puts the veteran no closer than 500, then we have to hold out the possibility and provide the Department of Veterans Affairs an answer that goes right with the veteran's statement and leave it to the VA, of course, to make the judgment in terms of all of the -- the available data as to whether weight is given

to an upper-bound estimate at 100 yards versus 500. And I think in the past we may have tried to enter ourselves into that judgment process more than probably we needed to. Again, this takes a lot of work and collaboration with understanding what the goals and objectives the Department of Veterans Affairs has and what are their considerations in making decisions.

MR. GRIFFON: Just one last follow-up on that. From what I understand, you didn't have a interview process for the claimants?

MR. SCHAEFFER: No, we do have an interview process.

MR. GRIFFON: You do have an interview process.

MR. SCHAEFFER: But if you looked at it over the entirety of the history of the program, there are various stages of inconsistency in how we did this, maybe less in the earlier days, more in the later days. In terms of how we do it today, we wouldn't want -- of course capture how we do it today, add a little more to it than what we have, but the important part is to develop a procedure by which we will do this in somewhat of a uniform fashion.

MR. GRIFFON: And is it a scripted interview now -- I

mean now, what you have, is it a scripted interview where you go through a set of standard questions with --

MR. SCHAEFFER: Give you an example of what we have, we have a basic questionnaire that we elicit from the veteran with basic name, address, where he lives, basic information as to what shot he thought he was at, and of course we send that back to the veteran and they confirm it and mail it back to us. In terms of what we did in the last eight years is we developed, in cooperation with the VA, a more extensive questionnaire that the VA can hand out to their claimants that we can also use when we talk to the veteran to go through and touch all the questions and elicit all the information. Is it a scripted interview by the type that you're talking about, much like NIOSH does? Not quite like that, but we do have a standard questionnaire.

MR. GRIFFON: Yeah, I actu-- the reason I brought it up was some of the accounts in the report -- I guess those were letters, maybe unsolicited letters from the claimants describing what incidents they were involved in and they have very in-depth descriptions of what

they did during those -- the tests, I guess.

MR. SCHAEFFER: Right.

MR. GRIFFON: And the -- I don't know if you couch it as in your current pro-- do you try to capture sort of work his-- you know, work history that way or do you ask them, I don't know -- I was just curious if you had a sort of standard set of, you know, questions along processes and potential exposures now or if it was more open-ended questioning --

MR. SCHAEFFER: Actually it's pretty specific. If you looked at the form that's in the VA workbook, as well as in our program, it's not only specific to what they did, it's specific to the types of test, whether they were on the test site, whether they were in the Pacific, whether they were in Hiroshima or Nagasaki, the forms are -- have different sectors that are peculiar to the differences in the types of testing.

MR. GRIFFON: That's what I was getting at. Thank you.

DR. ANDRADE: A quick comment and a quick request. I don't want to put you on the spot right now and hopefully when you report back it'll be interesting. Having come from a place that has recently been

accosted by the GAO, I know that they tend to make rash accusations based on little data. Two of them really strike me as completely frivolous. One is how in the world do they have the scientific bases to predict or to tell you that your beta to gamma factors are off by a factor of two or three? Same with the neutron to gamma factors. Okay? That means they must know a whole heck of a lot more about your study than yourselves. Nevertheless, I appreciate the program that you all are going to put together to try and address some of these issues, but I would really like to know what sort of basis they have stated to make these kinds of accusations. And not until the veterans are indeed interviewed, talked with -- their commanders interviewed, et cetera -- will anybody really have a clear picture as to what really happened out here.

MR. SCHAEFFER: Let me address your questions there 'cause I think both of those issues kind of stand apart from the program and where the current body of knowledge is. Let's take for instance neutron quality factor. It didn't say we failed to use a neutron quality factor. What it said we didn't do is, in the

upper-bound estimate of a neutron dose, take into account the body of knowledge as we know it today, reflecting the uncertainty on the quality factor. And I believe Dr. Kocher addressed that very well today as to what that truly means in terms of application to our program. Let's say we apply a quality factor of ten, we don't put in the upper-bound estimate that could have -- be as high as 20 and as low as five. Similarly for the skin dose factor that goes hand in hand with the fact that the skin dose is based -- part of that external exposure to the skin is based on the upper bound of the gamma estimate. And one of the areas of the report indicated that our upper bounds are somewhere on the order of 1.2 to 1.5, for instance -- I hope I'm quoting that correctly -- and the dose should be perhaps along the order of magnitude of two to three. Put that in the context in the fact that we use the upper-bound estimate to come up with the skin dose. That's where that particular comment is being addressed, as well as of course any uncertainties in the quality factor.

DR. ZIEMER: Okay. Thank you very much. We appreciate

this early review of the report, and we'll look forward to hearing more on it later.

BOARD DISCUSSION/WORKING SESSION

REVIEW PROCESS OF COMPLETED DOSE RECONSTRUCTIONS

Now we're going to move our attention to the dose reconstruction work group again, Mark. We do want to only go till 4:15 on this, so you want to pick up where you left off this morning or -- or is there enough time for you to do -- I can -- we can move the public comment period up if you'd rather not -- can you get enough done in 20 minutes to make it worth doing this afternoon?

MR. GRIFFON: No.

DR. ZIEMER: Okay, and then we'll defer your things until tomorrow then -- 'cause we have a session tomorrow. You have more to cover than you could in 20 minutes and you have handouts that will come tomorrow.

MR. GRIFFON: I'll have handouts tomorrow morning. It'll be easier for people to look at something.

DR. ZIEMER: Okay. Then we will ask for the ledger of public comment participants. Just a moment here.

(Pause)

PUBLIC COMMENT PERIOD

DR. ZIEMER: Okay, our first individual will be Richard Miller. Richard, from GAP, Government Accountability Project. Richard?

MR. MILLER: Hi, it's another city. It's Richard Miller, for the record. And there's no breeze blowing over the table today, too, I noticed, Dr. Ziemer.

DR. ZIEMER: There may be now.

(Laughter)

MR. MILLER: There's no evidence to support that at this time, though, Dr. Ziemer, is there? You're generating it at your end?

It's good that I don't work for GAO, I must say. First I just would like to -- 'cause we had a chance to listen to all of those wonderful conference calls on the Special Exposure Cohort rule, it's the kind of thing you almost want to stay up late to listen to. But you all -- I just wanted to just reflect on one thing, which was that I -- although I have not seen the letter, and I don't know whether it could be made available here for public dissemination, or maybe you all have it, but -- pardon? Whose web site? When?

MR. ELLIOTT: Pardon me?
MR. MILLER: Is it on the web site, did you say?
DR. ZIEMER: I don't know if it's on the web site yet.
MR. ELLIOTT: Is that the Board's letter?
MR. MILLER: The Board's letter, yeah.
MR. ELLIOTT: To Secretary Thompson --
MR. MILLER: Yes, Secretary Thompson --
MR. MILLER: Yes.
MR. ELLIOTT: I believe it's on the web site.
MR. MILLER: As of when? Okay. All right, we'll look again. Okay. Well, I think what you agreed upon was that the statutory intent of Congress was to -- that the 22 listed cancers was in fact a fixed list and whatever -- whatever caveats you had, you at least -- it appeared from what I heard and the rumor mill that this was the view that the Board had reached as a consensus, and if that was the case, I hope that NIOSH takes that and HHS takes that to heart.
I would just like to reflect on something that Dr. Melius had raised, which was with respect to the incorporation of worker studies. And if I understood the response, at least from Mr. Elliott was we'll take

up the question of worker studies after BEIR VII. And if that's right and if BEIR VII is say two years from now or a year and a half from now, we're looking at five years after the statute's been enacted before NIOSH begins to look at worker studies in its compensation model. And I just wanted to reflect and remind that the statute, in terms of setting the guidelines -- which is your IREP model -- requires that you at least take into consideration information on the risk of developing radiation-related cancers on work place exposures, and I know you all are familiar with it, but it just sort of struck me sitting there, we're going to have to wait five years to deal with that question. Seems to be a long time, and I thought Owen Hoffman's suggestion was really quite constructive, which is there's -- there are a number of studies out there which have come to multiple conclusions, and I'm not talking about a single study, but multiple studies that have raised questions, for example, as we've discussed in the past, age at exposure. Is the slope positive or negative with respect to age at exposure, and -- and the IREP model in some cases is linear and

in some cases it assumes that people are less radiosensitive the older they get. And -- and yet there are four or five studies out there now by three different authors, some of which were funded by NIOSH from the HERB branch, which seem to indicate well, there's a lot of uncertainty in this area, that -- that what we learned about the atomic bomb survivors and what we learned about workers are very different, that you have a positive -- you may have a negative slope, not a positive slope. And if that's the case, is there a way that, you know, SENES or others can propose ways in which those studies, where there are multiple studies -- not a single study but where there are multiple studies that seem to confirm that point, and it's a worker study -- that that can be accommodated sooner rather than later, because the effect, for example, on age at exposure is so stark. And yet we've got studies out there which seem to cast significant findings on worker studies that are different than those who were atomic bomb survivors, and we know a lot of the issues that came up with the atomic bomb survivors that may explain why you have a different

result for worker studies than you have from atomic bomb survivors such as the healthy survivor effect. But I would just like to propose at least for the Board to think about grappling with this sooner than waiting for BEIR VII, 'cause it seems like that's a long time to wait subsequent to enactment.

The second question I guess I would be interested to hear about would be the -- the weight of evidence around chronic lymphocytic leukemia. The only reason I guess this sort of keeps coming to my attention was -- was -- 'cause I keep getting all these letters from claimants who FAX them to me at home and say -- from the Department of Labor that says Dear So-and-so, The probability of causation from chronic lymphocytic leukemia is zero.

So, you know, curious about the CLL debate and going back to BEIR V, what we discover is that the statistical question before BEIR V was do we have enough cancers that are in excess of what was expected for that population, and there were two CLL cases identified in the life span study for mortality, and there was an expectation of 2.83 deaths from CLL. Now

I don't know if that's a statistically stable estimate, but I don't think it looks that way to me. It looks like a very unstable estimate, and there are a number of questions about the misclassification of CLL as it is. I mean, you know, hematologists and others will tell you it's easy to misclassify it for a number of reasons. And there are a number of others who have written on this subject extensively about how to treat all of the leukemias, and so I would just like to ask the Board to -- and maybe NIOSH -- to think about whether or not it is worth opening the inquiry, because I don't know that it's sustainable to say -- I don't know that it's defensible to say there's a zero percent probability of causation from any radiation exposure. Now in Germany just recently a court in northern Germany found, based on the work of Wolfgang Hoffman, who I've now learned is not related to Owen Hoffman, is -- has -- has -- has developed an extensive review both of literature and -- at the cellular level and epidemiologic level to indicate that in fact -- this was in a particular case involving an individual who had up to 400 rem -- was an X-ray technician -- that

this was a work-related radiation-related injury. Now if that's the case, and granted, it is merely a court decision and -- and -- and it was not -- but was based on, you know, the scientific weight that was brought to the table in that case, is this something worth opening up and looking at at this point, or is it a matter where the book is closed because it was closed in BEIR V or because Charles Land says it's not going to go into IREP? And I would just urge you all to think about that question and add it perhaps to that lengthy list of to-do's.

Those are my comments. Thank you very much. And I want to also compliment the NIOSH and their staff for putting together a terrific meeting in terms of information, the wealth of individuals you brought here, so thank you very much.

DR. ZIEMER: Thank you, Richard, for your comments. Let me ask if any of the Board members have questions to ask of Richard? There appear to be none. Thank you.

Next we'll hear from Denise Brock, who represents United Weapons Workers and Denise is with us from St.

Louis.

MS. BROCK: Hi, and I ask everybody to bear with me. I took notes while I was sitting here so I'll be shuffling and reading at the same time. It does not go in really good order. And for the record, my name is Denise Brock, and I do represent the United Nuclear Weapons Workers of the St. Louis region. I am here on behalf of all of Missouri Mallinckrodt workers. My mother is one of those claimants. I think the Board has met her. She is 80 years old and, for the record, she has had her phone interview in December and is still waiting dose reconstruction.

Today I do have some comments to make, as well as some questions to be raised. First of all, I would like to state that this is just not about science. It is also about sick workers, dying workers, and the survivors of deceased workers. And in some cases it is also about incomplete science, things like -- or for example, Mallinckrodt. I would like to give just a brief time line -- there is a method to my madness.

In April, 1942 Dr. Arthur Compton, a physicist from Washington University, met with Edward Mallinckrodt,

Jr. to ask if Mallinckrodt would sign onto a top secret project purifying uranium for making the atomic bomb. Mallinckrodt agreed, and Mallinckrodt thus steps into the forefront of the Manhattan Engineering District, later known as the Manhattan Project.

Here we go with the paper shuffling. One of the first goals of the Manhattan Project was to build an atomic pile to see if the theoretical chain reaction would actually work. The scientists figured that they would need 40 tons of uranium oxide and six tons of uranium metal, along with graphite, to build the pile. By July, 1942 Mallinckrodt Chemical in downtown St. Louis was producing a ton of pure uranium oxide a day. The magnitude, scope and danger of this effort was unparalleled. Using the highest grade uranium ore, known as Belgian Congo pitchblende, allowed the Project to proceed quickly. The government's ambitious efforts to build this atomic pile or atomic weapons supply later took some of the very lives they were intending to save.

For 24 years Mallinckrodt used 3,300 employees to produce more than 100,000 tons of purified uranium

metals -- or materials. At the outset Mallinckrodt was concerned about explosions from the ether used in the purification process. I understand that in Plant 4 they were using this to make pure uranyl nitrate.

The early absence of knowledge about the dangers of radiation led to some very cavalier approaches to the management of radioactive waste, not to mention the way in which Mallinckrodt workers handled these substances. For example, when they were handling this Belgian Congo pitchblende, the workers would take it off rail cars into the plant for processing with little protection other than cotton respirators and cotton work clothing.

July of 1942 Mallinckrodt is producing a ton of pure uranium daily, but workers are told that they're working with uranium oxide SL42-17. Code names like green salt, tube alloy, biscuit, juice, oats, cocoa and vitamin were given to the various processes, and no one was to say uranium. It was top secret. No one really knew what they were working with.

And somewhere between 1943 and '45, workers were told that they were performing a patriotic duty. The

Federal government built three cities for secret bomb-making -- Oak Ridge, Tennessee; Hanford, Washington; Los Alamos, New Mexico. In less than two years Mallinckrodt sends materials to all of them, and this is just a timeline of part of that.

And back to the workers, I must reiterate what I've said in previous meetings. Claimants get letters stating that it could be months or years before dose reconstruction is completed on their claims. These people do not have months or years. They are dying. I have workers that have cancers that have came back. I have workers -- claimants that have died while waiting for this -- to get finished with their dose reconstruction.

Most recently there has been an influx of Mallinckrodt claimants getting ready to have their phone interviews. This on one hand is a positive thing; it shows movement. But the unfortunate thing is these claimants are being sent questionnaires that they claim they cannot possibly answer, for several reasons. One was what I previously stated. These workers weren't told what they were working with. They were -- I say lied

to while they were being poisoned. They weren't monitored for all radionuclides or isotopes. And then you're looking at survivors of these workers. When the workers maybe that actually had an idea what they were working with were told to keep it secret and they took those secrets to their grave, this leaves the survivors. You're talking about 70 to 80-year-old people having to know things like this. It's almost impossible. I have claimants, survivors, women calling me crying or coming to my house saying I'm never going to get paid, this is a hoax, this is ridiculous, I'm just going to give up. I've got people that have cancer that are having to have $1,800 shots. I've got a mother that can't afford her medicine. She's had a quadruple bypass, and it's not an anomaly. These people are sick and are waiting for this to be expedited, and it's not happening. And I don't think it's on purpose. I don't think it's with malice or forethought (sic), but it is the truth. It just -- it seems like it's stagnating or laying somewhere. I've got workers that are living that are sent questionnaires that are -- it's actually I think page

four, I believe, on the questionnaire, and it actually says on there which radionuclides were you exposed to, things like tritium, cobalt, actinium, protactinium, polonium. These workers don't know what that is. Next -- and then it says you can answer yes, no, don't know. All respect to Dr. Toohey, he's wonderful. I did call him. I had two claimants actually at my house, two older men that are very sick, just on the verge of tears saying I have no idea what this is. I don't know. I wasn't told. So I talked to Dr. Toohey and of course Dr. Toohey said they can say no or don't know, and obviously they're concerned if they do that, that somehow is going to have a negative effect on their dose reconstruction. That, too, would be my concern. Then you've got something next to it that says isotope. They don't know what an isotope is, and then it says solid, liquid or gas. And my question to Dr. Toohey was, if this stuff concentrated, we don't know if or where, could that form change? I mean this is an awful lot for these 70 and 80-year-old sick workers or survivors of such to know.

So what I did was I researched what radionuclides went

with what facilities, and I put a key there because we have three Mallinckrodt facilities. And there wasn't enough room, so I made my own paper, then I got the isotopes and I filled all that out and I called a meeting for those that were getting ready to have their interview and I gave that to them so whoever interviews these people will be prepared because these people do know now what they were exposed to that they didn't know then.

And my question, too -- I do have a question. Some of the claimants have, as well. Once that phone interview's done -- like I said, my mother had hers in December -- the question would be I guess is there a site profile completed on Mallinckrodt yet? Is that -- is that finished, completed?

MR. ELLIOTT: No, it's not completed. It is being worked on.

MS. BROCK: Being worked on. I understand, but I guess my confusion here is if there's limited to incomplete individual data -- for example, I filed a FOIA request on my father on behalf of my mother, and I got a call from the Department of Energy stating that they did not

have the records or access to such, would I like to withdraw my FOIA? I said absolutely not. If you don't have it, then you put it in writing. I'll take it to my senator.

Well, then I get a letter in the mail -- actually, I'm sorry. Then I understand that they said by not having access, the Department of Energy did not own those records, the vendor did, and I believe there's a statute that says that DOE is to go to that vendor. Well, we have a problem there because Mallinckrodt was bought out by Tyco*. We have all sorts of problems. Make a long story short, I get something back from the Department of Energy stating my dad was under Q clearance and they've destroyed his records. This again is not an anomaly. My concern here is if you've got workers and their records are destroyed and they've had multiple job titles, multiple exposures, how are you going to dose reconstruct them? I have grave concerns. I'd like -- I've said this in the past about using coworker data. I have workers telling me badges were laundered. I have no idea what that means. And if you're basing this on site information, we had

actinium, protactinium. I recently found out we even had beryllium. I mean if -- if the health physicists are aware of this, why are you asking the workers when they have no way of knowing this?

DR. NETON: I'd just like to maybe clarify a little bit. The purpose of the questionnaire is really not to have the claimant provide a detailed response to us, although that would be certainly beneficial to us. But it's really just to get the record -- a complete record. We felt that it's very important for the claimant to be able to represent what they felt they were exposed to or what they were exposed to, so we could compare that to the record that's in the Department -- the Department of Energy provides. In no way is -- are we relying solely on the claimant's response to the questionnaire to complete a dose reconstruction.

MS. BROCK: The next thing I wanted to say was that I understand Mallinckrodt produced a residue containing radium in the process of recovering uranium from the Belgian Congo ore. This residue was known as K-65 residue. In 1949 about 200 pounds of this residue was

shipped to Mound, Ohio. Eighty drums of rather inhomogeneous material was supplied by Mallinckrodt known as Sperry presscake, which consisted of a matrix of iron, protactinium, aluminum, calcium, magnesium, cobalt and copper. Kotter* Company also received 100,000 tons of material from St. Louis, possibly tailings in the '60's and '70's. These were from the Belgian Congo processing. During the Dodge v. Kotter trial a deposition was taken of a Kotter manager where he admitted that materials from St. Louis had plutonium in them. I'm assuming that must have been -- because I've recently researched and found it was PU-244. I'm not a scientist or health physicist, so I hope that's correct. I understand that's a natural-occurring plutonium, and I understand that maybe there was a criticality underground in Africa that could have caused that. I'm not quite sure if that's correct. I would also publicly like to state again -- and please don't anyone take this personally, but I just feel that Mallinckrodt should be a Special Exposure Cohort, especially if there are only two criteria needed to meet that. Number one, that the workers were

endangered. I think that's a given. And number two, that NIOSH cannot dose reconstruct with sufficient accuracy. And Senator Bond, which is a senator in Missouri, will actually be flying in his DC Labor person on the 27th to talk to me about that I've briefed their office once, and I am hoping with everything I have that -- that this goes through because, to me, these workers are dying. It would be the quickest way -- it would expedite this. But beyond that, they were exposed to things they were never monitored for. And unless Larry wants to tell me he can go ahead and just slap a 150 to all of them, I just think that would be the best way for me to do that. I just have a couple of questions if you -- am I taking too long?

DR. ZIEMER: You're okay, Denise.

MS. BROCK: Okay. Dr. Neton said that the site profile was not finished yet. Could you tell the Mallinckrodt workers, do you have any idea -- how long do you think it will be before the site profile is done or what else -- I understand you're getting ready to go to SLU, or St. Louis University, and then possibly to Georgia to

collect more evidence or more information or data. Do you have any idea how long it will take to finish this profile before you can start dosing these workers?

DR. NETON: I think the site profile has been started on Mallinckrodt. I know it's been started -- I would -- I can't give you an exact time frame, but I would say it's a matter of months, in the next several months it's on the agenda to be finished. We had recently completed a data capture effort at the DOE Germantown office where we found boxes of Mallinckrodt monitoring records that we're going through and assembling. As you know, ORAU -- Mallinckrodt has also been studied extensively by ORAU, our contractor, in previous epidemiological studies, so there exists a large volume of records there. So the short answer is that there -- there's a tremendous amount of -- a large amount of information available at Mallinckrodt that we need to review to develop the site profile. And it in general is to the claimant's benefit that we do that so that we can make sure that the doses that we assign are accurate, and in fact that we do contribute a missing dose to their records that may have not been captured

in the monitoring program. But it will be a matter of several months before it's completed.

MS. BROCK: And I agree. I mean I would hate to see a site profile rushed through. I mean you want to make sure that it's not incomplete, that there are things there. But my concern, too, is if there are things that these workers are not monitored for, such as the actinium and protactinium, we've got three types of radium, three types of radon gas, just enormous amount of things. I know that you say you can use site information to dose these workers, and maybe use a worst case estimate. How do you keep from underestimating that worst case? Maybe I'm just confused, but I don't understand how you do that.

DR. NETON: Okay, it has to do with the uncertainty distribution, which we've seen a lot of evidence discussed today with Dr. Kocher's presentation, but it's similar to that -- to that process. We take a look at the available evidence related to the monitoring information, and if there is no monitoring information on the workers, we'll look at the air sampling information. And using that, we'll take a --

we'll make a best estimate, a best judgment of what the most likely exposure scenario was in the work plant. But then we will assign a distribution of values about that. And in sampling for the probability of causation, when it's run through -- we'll assign that distribution about the central estimate, and then when the Department of Labor runs the probability of causation calculation, it will use that distribution of all possible exposures to come up with the probability of causation. So it's sort of built into the model.

MS. BROCK: Hypothetically speaking, if I would get this SEC to go through, what happens if claims are actually dose reconstructed and denied? Is there a possibility that I could help those people that have been denied? Can they later go into the Special Exposure Cohort? Is that a possibility?

DR. NETON: The rule makes a provision for any time new information comes forward, it provide -- either discovered by NIOSH or provided by the claimant, Labor can reopen the claim and re-evaluate it at that time. So that's a definite possibility and that's provided for.

As far as once the claim has been denied and then being moved over to the Special Exposure Cohort, I'm not sure. Maybe Ted Katz could shed some light on that issue.

MR. KATZ: I mean if -- if they're denied it through dose reconstruction and then they're added to the Special Exposure Cohort, there's a lot of steps in between that that would explain that, but certainly if they're added to the Special Exposure Cohort, then they would be compensable claims under the provisions of that cohort, yes.

MS. BROCK: I only have like three more questions, sorry.

The 22 cancers, I understand there's only 22 cancers in the Special Exposure Cohort. I do have numerous people with prostate cancer, skin cancer. If the Special Exposure Cohort goes through and you're saying dose reconstruction cannot be done with sufficient accuracy, those people fall through the cracks or are they dose reconstructed?

MR. ELLIOTT: We are doing dose reconstructions on prostate, skin, for the current SEC cohort members.

These folks that you've identified for future classes to be added to the cohort would then be without remedy at that point because we would be in a position where we've said we could not do dose reconstruction for that class.

MS. BROCK: Are you saying that prostate and skin are part of the 22 cancers? Did I misunderstand that?

MR. ELLIOTT: No, no.

MS. BROCK: No.

MR. ELLIOTT: I'm saying that currently we are doing dose reconstructions for members of the Special Exposure Cohort who present with prostate, skin and other cancers not of the 22. Now that's what's going on now.

Once the rule -- our rule on Special Exposure Cohort classes is in place and we add a class to the Special Exposure Cohort, that is under the premise that we can't do dose reconstruction. So unfortunately, at this point, those folks who present with a cancer not on the list of 22 would be without remedy.

MS. BROCK: Okay, thanks. Now this sort of has to do with the Special Exposure Cohort, too, I guess, and not

to beat a dead horse because I've brought this up before, but we had talked about this smoking. And I noticed today that one thing that wasn't mentioned was a former smoker, and I understand that RECA actually removes the smoking in 2000, so I just think -- I'm confused. Isn't it merely to be a consideration? I know with smoking it's an automatic pay in the SEC, so I'm wondering again if you've got two workers side by side, they both present lung cancer, one's a smoker, one's a non-smoker, where's the equity? I mean nobody's disputing that smoking causes cancer. It's about equity, and I'm not understanding how that's equitable.

MR. HENSHAW: Russ Henshaw, NIOSH. I'm not sure, Denise, if I can answer this question this time any better than last time, but I guess all I would say is that smoking in lung cancer is one of the issues we're going to reconsider in the future, and hopefully incorporate additional studies such as the Pierce study that Owen Hoffman reviewed earlier. But beyond that, I don't think there's anything we can add to that at this point.

MS. BROCK: Just two more. The bone cancer, I was just a little bit confused as I don't know if that pertains to us or not. If you have -- are you saying that the latency period should be lowered to five years? Is that right, that if a person contracts or diagnosis -- right now is it ten years? It should be lowered to five?

DR. ZIEMER: Owen or one of the SENES people may want to address that. My recollection is that they were saying the latency period perhaps should be shorter, which would be more claimant-friendly, by the way.

DR. HOFFMAN: Yes, I -- it was in Iulian's presentation this morning that this was brought up, and as a precursor to the details on thyroid cancer. But basically -- and NCI is doing this in the NCI version of IREP is -- is correcting the latency for bone cancer to allow for some probability of causation when the cancers would be presented much earlier than is currently considered. And the question is before NIOSH, to what extent is this a significant enough of an update that they would like their version to reflect that assumption as well.

MS. BROCK: Thank you. And the next two are just -- are just statements. One would be in reference to Shelby Hallmark from the Department of Labor stating that any help would be appreciated. I've actually talked with the Missouri -- the head of the Missouri Building Trades Council and they've actually asked me to come in and speak with them. They said that they thought that that would generate thousands upon thousands of claims, so I'm supposed to go talk with them when I get back, after Senator Bond's office, and that will cover the iron workers, construction, dismantling, cleanup, what have you, so I will be doing that next as well. Be really nice if you want to pay me, that would -- hook me up, that would be great. And I would also like to again ask the Board to please come and have a meeting in St. Louis because this is really tearing my budget up paying for all that paperwork I send out to people to generate claims, and then I have to try to get to these meetings, which I don't want to miss. But if you would come to St. Louis, it would be greatly appreciated and I'm sure I can drum up plenty of people for public comment. And

thank you very much.

DR. ZIEMER: Thank you, Denise. Mark, comment here?

MR. GRIFFON: I just wanted to comment on one of Denise's first points about the interview process and the question -- I mean it's come up in a couple of public commenters about maybe we need -- maybe these questionnaires, the interviews, could have a site-specific component or could have site-specif-- people that know these sites better to conduct those. And I don't know if any of that is happening, being considered, I -- I --

DR. ZIEMER: I thought that Dick Toohey spoke to that at the last meeting. I think the answer was yes, but --

DR. NETON: No, there's no site-specific component because it's an OMB-approved script that we have to follow. However, we do afford the opportunity, if the claimant suggests something that we could follow up on, we would do that. But at this point, we're not considering a site-specific script.

I will say that in general we're not requesting the claimant to go through -- it's not our approach usually

to go through an entire list of the periodic table and ask them if they were exposed or not exposed. The intent was to which nuclides, if you're aware, were you exposed, and that is a list that would be used to invoke maybe some memory. So it's -- and I think where the confusion arises, we mail this script at the time that the interview is going to be scheduled to the claimant, just so they can go over it and get comfortable with the lines of inquiry that we're going to be, you know, talk through. And I think some people receive the script and think that it's a detailed, blow-by-blow thing that they're going to have to know every answer, and that's maybe where the confusion arises.

MR. GRIFFON: I guess the -- the -- just reflecting on the last draft that came out about the interviews, or -- or the information from workers I guess. They weren't really interviews but a provided scripts or information of what they did on their jobs, and again and again, going through that report, I read that the analyst tend -- tended to downplay some of this -- and partially because, I think -- or one of their

conclusions in the report, and I may be summarizing this wrong, but I think was that pulling the string on all these things, to use your terminology, was going to be very extensive. So my concern is that this questionnaire process just doesn't become another check mark in the processing of these claims, but rather that NIOSH make -- there's some valuable information that can be pulled from these claimants, rather than saying well, if they can't answer it, we've got the answers. I mean I think that -- and I -- go ahead, Larry.

MR. ELLIOTT: I got to talk to this.

DR. ZIEMER: Response, Larry.

MR. ELLIOTT: Let's go back to the start here. You know, NIOSH -- I come forward and said we needed to have an interview process here. It wasn't part of the statutory requirement. We're very much interested in hearing what the worker has to say. We interview workers on the shop floor in all of our studies, in all of our hazard evaluations, and so why not use that experience in this program as well. We're very much interested in hearing what the worker has to say and we're not using it just as a check mark or checklist.

I'm sorry, I'm very passionate about this, but I need to be passionate about this because NIOSH needs to stand here and our integrity needs to stand up, and this is part of that. So we're taking this very seriously.

Could we do a better job on getting our interviews in the hands of the claimants? I think we can. I think we can do a better job of communicating the intent behind what we provide in advance of the interview, that it's not a -- we don't expect the claimant or the survivor of the claimant to have all the answers. But what we hope to be able to do is to help fill in some gaps that may not exist in the -- and probably don't exist, in all cases, in the DOE submittals that we get back in our requests for dose information. So that's the purpose and the intent behind this and I assure you we take it very seriously and we want to hear what the worker has to say.

DR. ZIEMER: That may be a key thing to make sure that -- 'cause there may be a mismatch here. It sounds like some of these survivors are thinking that the burden is on them to come up with all this technical information,

so somehow it's not made clear to them that this -- if you know something that we haven't culled out already, we want to hear what that is. But somehow that message needs to be communicated.

DR. NETON: I agree, I'd just like to comment on one of Mark's comments about the site-specific scripts. I mean I don't mean to imply we couldn't develop a site-specific script and get it cleared through OMB, but I think that we may sort of predispose the interview at that point, you know, if we had a specific list and we -- you know, then we wouldn't be able to pull out the -- if we had a script of nuclides at Mallinckrodt, say were you exposed to uranium and they came back and they had information and said no, I was exposed to plutonium, we wouldn't -- we wouldn't learn that. So we try to keep it as an open forum as possible in this process.

MR. GRIFFON: I'm not saying put words in their mouth, either, with a site -- you know, some sort of -- that you have -- you know, that kind -- but I think there could be ways to do it site-specific. And I'm not -- and I know NIOSH's intent is to get this information.

I just wanted to -- it's more of a reflection on this report that I was just looking at that we need to keep our eye on the ball with this and that they may not know -- I was just reflecting on the comments I heard about -- and my research that they don't know the radionuclides necessarily, but they have a lot of valuable information that they can provide that when I combine it with our other technical information it can really validate your scenarios and your site profiles and stuff like that. So that's all I was saying.

DR. ZIEMER: Okay. Thank you. Let's move on then. Our next commenter is Philip Foley who is with PACE, and Philip is here from Kentucky.

MR. FOLEY: I'm with the worker health program in Paducah, Kentucky, and I'm hesitant to speak, but after setting in this meeting, I feel I'd be doing my people, my coworkers, a disjust-- a injustice if I didn't say something.

We -- I have serious concerns with the dose reconstruction because what placed Paducah in the Special Exposure Cohort in the first place was that the data -- there's a lot of data available. Mark's gone

through a lot of data at Paducah. But it was shown that it was questionable, at best. And if I understand correctly, when you do a dose reconstruction, you're going to get this data from Paducah. Well, it's the same data that placed us in a Special Exposure Cohort. Just one -- I guess a for-instance. We had -- we've had some risk mapping sessions. We'd asked the gentlemen that were in releases, have you -- did they do urine samples? Say yes. Well, how soon? Twenty to 30 minutes after the release. So there's tons of data, but it was taken at the wrong time. So you know, you can look at this data and it will show that well, they -- they weren't exposed. But that's because it was taken too early.

There's a lot of things that you're not going to find out -- I personally spent three weeks with an air hose on top of a crane blowing all the dust and paint scale and everything out of the 400 building, which is a cleaning building, where they had a compressor shop, they had a spray booth, I think they had a -- we found out since, probably a neptunium trap, many things that they had in this building. You know, these are the

kind of things these people are up against.
I saw the same letter, their questionnaire, that Denise was talking about, and this gentlemen called me, was about a 55-year-old retiree from our plant, and he was upset. He was concerned because this page that listed all these isotopes, said have you ever been exposed to these. Well, you know, when I hired in in 1975 -- and I'm sure -- I know long before that, when we asked questions -- as an electrician, when I asked a question, they said you don't need to know. You know, this is national security. You don't have a need to know. So we didn't know what was going on.
Now since, in the last three years working in the worker health program, I've heard stories of these gentlemen, when they brought the spent reactor fuel from Hanford, stored it outside the control room in barrels. They didn't know what was out there. Some of them knew it was spent reactor fuel, but they didn't know what was -- you know, it was just setting out in the building. We had barrels of green salt all over our buildings. There's a lot of exposures that people probably weren't even tested for.

And I guess what I'm -- what my concern is, you know, we've been called cold war veterans. I've heard us called that and I've made this statement in a Congressional hearing for Senator Bunting and also in a DOE public meeting. You know, we're called cold war veterans, and all we're asking is just don't leave us out in the cold. You know, don't -- don't make us go through some of the things like Denise was talking about. We've got the 70, 80-year-old people. You know, they don't know -- if you do a phone interview with them, some of them that I talked with, you know, they don't have -- their attention span is not very long. They're not going to -- they're not going to be able to set and go through this phone interview. I set in on this gentleman with a phone interview and the interviewer did a fine job. He didn't ask leading questions. He listened to the guy. But I don't know what he reported. And all I'm asking is just don't leave us out in the cold. Help these people out.

DR. ZIEMER: Thank you, Philip. That concludes all the names I have on the public comment list. Are there any other individuals that were missed that I don't...

Okay, if not, let's quickly turn attention to tomorrow's schedule. The Board will be reconvening at 8:00 o'clock in the morning. We actually start our formal session at 8:30. There will be a session for -- basically for the Board. This is an ethics training session that we're required to go through.

We will have a working session where Mark Griffon will lead us through the next steps on the dose reconstruction process that we're preparing for the Board's quality assurance program, if I can use that terminology.

There will be additional opportunities for public comment tomorrow morning, as well.

Oh, and I'm sorry, I did miss -- we are going to have a report on the epidemiological research program of the DOE workers, so we will get a status report on that.

Thank you.

Also, tomorrow afternoon after the formal session, some of the Board members will be touring the Oak Ridge facilities. This will not be a formal Board meeting. There will be no business conducted, but an opportunity for some of the Board members to see some of the

facilities here in the Oak Ridge area.

I'm going to ask Cori if we have any additional housekeeping items that we need to take care of today.

MS. HOMER: Just don't leave anything in the room.

DR. ZIEMER: Yes, do not leave things in the room overnight.

So we'll now go into recess until 8:00 o'clock tomorrow morning. Thank you very much.

(Meeting adjourned)

C E R T I F I C A T E

STATE OF GEORGIA)
)
COUNTY OF FULTON)

I, STEVEN RAY GREEN, being a Certified Merit Court Reporter in and for the State of Georgia, do hereby certify that the foregoing transcript was reduced to typewriting by me personally or under my direct supervision, and is a true, complete, and correct transcript of the aforesaid proceedings reported by me.

I further certify that I am not related to, employed by, counsel to, or attorney for any parties, attorneys, or counsel involved herein; nor am I financially interested in this matter.

WITNESS MY HAND AND OFFICIAL SEAL this _____ day of June, 2003.

_____
STEVEN RAY GREEN, CVR-CM
GA CCR No. A-2102